IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

In re: Guidant Defibrillators Products Liability Litigation

Court File No. 05-md-1708

This pleading applies to:

ALL ACTIONS

PLAINTIFFS' FIRST AMENDED MASTER COMPLAINT FOR PERSONAL INJURY, ECONOMIC LOSS, THIRD PARTY PAYOR AND MEDICARE SECONDARY PAYOR ACT CLAIMS, INCLUDING CLASS ACTIONS

JURY DEMAND

INTRODUCTION

1. Plaintiffs, by their undersigned counsel and other counsel identified herein, for themselves and all others similarly situated, hereby bring this Master Complaint and the identified Class Action and individual claims against Defendants Guidant Corporation ("Guidant Corp."), Guidant Sales Corporation ("Guidant Sales"), Cardiac Pacemakers, Inc. ("CPI") and Boston Scientific Corporation ("Boston Scientific") (hereinafter collectively "Defendants" or "Guidant") for equitable, injunctive, and declaratory relief and monetary restitution and/or damages. Plaintiffs make the following allegations based upon their personal knowledge as to their own acts, and upon information and belief, as well as upon their respective attorneys' investigative efforts as to Guidant's actions and misconduct.

2. This Master Complaint is submitted pursuant to the Case Management Order of this Multidistrict Litigation ("MDL") Transferee Court, to serve only the administrative functions of efficiency and economy of presenting certain common claims and common questions of fact and law for appropriate action by this Court, including trial, in the context of this multidistrict

proceeding. This Master Complaint does not include all claims asserted in all of the actions that have been transferred to this Court under 28 U.S.C. § 1407, nor is it intended to consolidate for any purposes the separate claims of the plaintiffs herein. Those matters are set forth in the individual and class actions filed by each of the respective Plaintiffs. This Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted therein, nor by it do any Plaintiffs, including those named herein, relinquish the right to add or assert or seek leave to add or assert any additional claims or predicates for claims depending on further discovery or information that they may learn.

SUMMARY OF GUIDANT MISCONDUCT AND RESULTING DANGERS, DAMAGES, INJURIES, AND CLAIMS

3. This Master Complaint, filed on behalf of the Plaintiffs presently in, or who may hereafter join, this MDL, summarizes and sets forth an unparalleled story in American medical history that has been on the front pages of the nation's newspapers for nearly a year. As recognized by the doctors who were impaneled by the company itself to review its actions, Guidant Corp. is a major medical device company that viewed human beings as mere engineering statistics and consistently believed that its primary goals were to maximize profits and attain maximum market share through the continuous introduction of new – even if inherently defective – products. As a consequence, Guidant Corp. and its related entities, the Cardiac Rhythm Management Division ("CRM Division"), CPI, and Guidant Sales routinely failed to inform customers of the risks inherent in its products; believed that it – and not patients' medical care providers – could and should determine what risks patients should know about; violated state and/or federal law; engaged in improper manufacturing processes; used materials that were unfit for the purposes for which Guidant utilized them; and even, as in the case of at least one illustrative device, the Guidant Ventak Prizm 2 DR implantable cardioverter defibrillator ("ICD") Model 1861, continued to sell

defective units it knew might lead to serious injury or death in order to sell out its remaining inventory of the device.

4. In April 2006, Guidant's shareholders approved its acquisition by Defendant Boston Scientific. On April 21, 2006, Boston Scientific's acquisition of Guidant was completed. Through that acquisition, Boston Scientific assumed all the liabilities of Guidant in connection with this litigation, and will henceforward be legally liable for the wrongdoing of Guidant as it existed prior to the close of that acquisition.

5. As yet, the full Guidant story remains unknown, as discovery has only recently commenced in earnest. Nonetheless, there is more than ample evidence revealing that Guidant's actions demonstrate a profound and endemic disregard for basic and well-established medical and ethical standards. The serious consequences of Guidant's conduct are underscored by the fact that the devices at issue were devices that human beings – not statistical artifacts as Defendants viewed them – had implanted in them through open chest surgeries with the intention that patients rely on the devices, literally, to permit their hearts to beat.

6. Guidant's deliberate disregard for medical and ethical norms led to actions that breached a wide array of legal principles. The claims set forth below sound in tort, contract, consumer and business protection statutes, and equity. Because a significant percentage of Plaintiffs are elderly, this litigation also implicates laws providing special legal protections for senior citizens.

7. The claims at issue include damages for personal, emotional and psychological injury, and death, as well as claims for economic damage and restitution arising from Plaintiffs' rights to return of the full costs of their devices, related surgeries, and the costs of replacement.

8. Not only have some individuals died, but many thousands have suffered great and unwarranted emotional and psychological distress and many thousands more have a legal right to seek repayment of costs they incurred and a claim against the massive profits and revenues that Defendants garnered from their wrongful conduct. Plaintiffs whose claims are asserted in this Master Complaint thus include many thousands of natural persons who were implanted with one or more Guidant heart devices and/or their families, survivors, or estates ("Device Recipient Plaintiffs").

9. This Master Complaint includes claims of third party payors such as health and welfare funds, self-insured employers, and non-profit and for-profit health insurers, all of whom bear the ultimate economic risk of health care payments ("third party payors" or "TPPs"), against Guidant, for its sale and distribution of defective heart devices, and for its otherwise wrongful marketing, promotion, advertising and sale of these devices. By reason of the wrongful conduct of Guidant, a massive, national recall of heart devices has been underway in the United States. Public and private payors of health insurance have had to shoulder, wrongfully, an enormous economic impact of Guidant's conduct, an amount that is in the hundreds of millions of dollars.

10. All Plaintiffs are entitled, for the reasons below – and for the supplemental and additional reasons that will be uncovered through discovery – to prevail in substantial measure, whether on an individual or class basis. Significantly, this litigation also involves important medical, ethical and societal issues, which were recognized by the Report of the Independent Panel of the Guidant Corporation issued on March 20, 2006 ("Independent Panel Report").

11. Plaintiffs hope that this litigation may be the last of its kind, and that once the full panoply of Guidant's actions is brought to light and redressed by law, other medical device

companies will treat patients and their medical professionals with forthrightness, respect and candor under an ethical and legally sound paradigm.

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PARTIES

Device Recipient Plaintiffs

13. Plaintiff John Boland is a citizen and resident of the Commonwealth of Pennsylvania. Mr. Boland is represented by the law firm of Lieff, Cabraser, Heimann & Bernstein, LLP. Mr. Boland has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about April 10, 2003, Mr. Boland was implanted with a Guidant Contak Renewal cardiac resynchronization therapy defibrillator ("CRT-D") (Model H135). On or after June 17, 2005, Mr. Boland first learned that the Guidant Contak Renewal defibrillator implanted in his body had an irregularity that could result in its failure to function. Mr. Boland suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant Contak Renewal defibrillator, and knowledge that he might have, at any time, been fatally injured because of its malfunction. In addition, he was very concerned that he might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. On or about June 27, 2005, Mr. Boland's Guidant Contak Renewal defibrillator was replaced. Mr. Boland suffered injuries and damages as a result of the explantation of the defibrillator.

14. Plaintiffs Jamie Brennan and René McCollick, as co-administrators of the estate of John Brennan, are individual citizens and residents of the Commonwealth of Pennsylvania, and bring this action in substitution for their late father, John Brennan. Jamie Brennan and René McCollick are represented by the law firm of Lieff, Cabraser, Heimann & Bernstein, LLP. Mr. Brennan died on July 3, 2005. Mr. Brennan had severe heart disease, which necessitated the use of an ICD. On or about April 11, 2001, Mr. Brennan was implanted with a Guidant Ventak Prizm 2 DR ICD (Model 1861). On or about May 24, 2005, Mr. Brennan first learned from news reports that the Guidant Ventak Prizm 2 DR ICD implanted in his body had an irregularity that could result

in its failure to function. Mr. Brennan suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant Ventak Prizm ICD, and knowledge that he might have, at any time, been seriously, if not fatally, injured because of its malfunction.

15. Plaintiff Christofer Brewster is a citizen and resident of Allendale, Michigan. Mr. Brewster is represented by the law firm of Kershaw, Cutter & Ratinoff, LLP. Mr. Brewster has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about April 26, 2002, Mr. Brewster was implanted with a Guidant Ventak Prizm 2 DR ICD (Model 1861). On or after June 17, 2005, Mr. Brewster first learned that the Guidant Ventak Prizm 2 DR ICD implanted in his body had an irregularity that could result in its failure to function. Mr. Brewster suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant Ventak Prizm 2 DR ICD, and knowledge that he might have, at any time, been fatally injured because of its malfunction. In addition, he was very concerned that he might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. On or about July 12, 2005, Mr. Brewster's Guidant Ventak Prizm ICD was replaced. Mr. Brewster suffered injuries and damages as a result of the failure of the Guidant Ventak Prizm 2 DR ICD to function properly and as a result of the explantation of the defibrillator.

16. Plaintiff Professor Eugene Clasby is a citizen and resident of the State of Florida. Professor Clasby is represented by the law firms of Harke & Clasby, LLP and Barnow and Associates, P.C. In December 2002, Professor Clasby had a Guidant Ventak Prizm 2 DR ICD (Model 1861), implanted in his body, as a result of a massive congestive heart infection. On or about June 2005, Professor Clasby first learned that the Guidant Ventak Prizm 2 DR ICD implanted in his body had an irregularity that could result in its failure to function. Since the implantation, the device has shocked him without cause at least once and he has been taken to the hospital for

treatment. Professor Clasby suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant Ventak Prizm 2 DR ICD, and knowledge that he might have, at any time, been fatally injured because of its malfunction. He has been prescribed anti-depressants and anti-anxiety medication to help him with these issues. In addition, he is very concerned that he might get a life-threatening infection of the heart, endocarditis, as a result of any replacement surgery. To date, Professor Clasby's Ventak Prizm 2 DR ICD has not been explanted.

17. Plaintiff Paul Jones is a citizen and resident of the State of Michigan. Mr. Jones is represented by Theodore J. Leopold, Esq. Mr. Jones has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker. On or about June 16, 1999, Mr. Jones was implanted with a Guidant DISCOVERY pacemaker (Model 1273). On or after July 18, 2005, Mr. Jones first learned that the Guidant DISCOVERY pacemaker implanted in his body had an irregularity that could result in its failure to function. Mr. Jones suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant DISCOVERY pacemaker, and knowledge that he might have, at any time, been fatally injured because of its malfunction. In addition, Mr. Jones was very concerned that he might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. On or about, August 8, 2005, Mr. Jones' Guidant DISCOVERY pacemaker was replaced. Mr. Jones suffered injuries and damages as a result of the explantation of the pacemaker.

18. Plaintiff Zina Lewis is a citizen and resident of the State of Utah. Ms. Lewis is represented by the law firm of Lieff, Cabraser, Heimann & Bernstein, LLP. Ms. Lewis has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker. On or about July 15, 2003, Ms. Lewis was implanted with a Guidant INSIGNIA pacemaker (Model 1297). On or after July 18, 2005, Ms. Lewis first learned that the Guidant INSIGNIA pacemaker

implanted in her body had an irregularity that could result in its failure to function. Ms. Lewis, who is 100% pacemaker dependent, suffered extreme emotional distress as a result of the knowledge of the defective nature of her Guidant INSIGNIA pacemaker, and knowledge that she might have, at any time, been fatally injured because of its malfunction. In addition, she was very concerned that she might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. On or about November 22, 2005, Ms. Lewis' Guidant INSIGNIA pacemaker was replaced. Ms. Lewis suffered injuries and damages as a result of the explantation of the pacemaker and complications following the surgery.

19. Individual and representative Plaintiff Judy Passante is a citizen and resident of the State of Florida. Ms. Passante is represented by Theodore J. Leopold, Esq. Ms. Passant has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about February 1, 2005, Ms. Passante was implanted with a Guidant Contak Renewal CRT-D (Model H170). On or after June 17, 2005, Ms. Passante first learned that the Guidant Contak Renewal CRT-D implanted in her body had an irregularity that could result in its failure to function. Ms. Passante suffered extreme emotional distress as a result of the knowledge of the defective nature of her Guidant Contak Renewal CRT-D, and knowledge that she might have, at any time, been fatally injured because of its malfunction. In addition, Ms. Passante was very concerned that she might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. On or about December 7, 2005, Ms. Passante's Guidant Contak Renewal CRT-D was replaced. Ms. Passante suffered injuries and damages as a result of the explantation of the defibrillator.

20. Plaintiff Mati Peleg is a resident of Netanya, Israel. Mr. Peleg is represented by the law firm of Lieff, Cabraser, Heimann & Bernstein, LLP. Mr. Peleg has a severe cardiovascular

condition that requires the use of an implantable cardiac pacemaker/defibrillator. Mr. Peleg was implanted with a Guidant Vitality AVT defibrillator (Model A155) on March 22, 2005. On or after June 17, 2005, Mr. Peleg first learned that the Guidant Vitality AVT defibrillator implanted in his body had an irregularity that could result in its failure to function. Mr. Peleg is currently in consultation with his physicians for the purpose of determining whether the risk to his life from explantation surgery is greater or less than the risk to his life of leaving the Guidant Vitality AVT defibrillator in place. Mr. Peleg is suffering extreme emotional distress as a result of the knowledge of the defective nature of his Guidant Vitality AVT defibrillator, and knowledge that he may, at any time, be fatally injured because of its malfunction.

21. Plaintiff Jeffrey Schacher, as personal representative of the estate of Marvin Schacher, is a resident of the State of Colorado, and brings this action in substitution for his late father, Marvin Schacher. Jeffrey Schacher is represented by the law firm of Burg, Simpson, Eldredge, Hersh & Jardine, P.C. Mr. Marvin Schacher had a severe cardiovascular condition that necessitated the use of an implantable cardiac pacemaker/defibrillator. On or about January 30, 2004, Mr. Marvin Schacher was implanted with a Guidant Contak Renewal CRT-D (Model H177). Mr. Marvin Schacher suffered inappropriate firings of the Guidant Contak Renewal CRT-D while he was alive, and then failure of the Guidant Contak Renewal CRT-D to fire when it was needed, resulting in his death two months later, on March 4, 2004.

22. Plaintiff Thomas Shreiner is a citizen and resident of the State of North Carolina. Mr. Shreiner is represented by the law firm of Douglas & London, P.C. and Parker & Waichman, LLP. Mr. Shreiner has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about November 4, 2003, Mr. Shreiner was implanted with a Guidant Vitality AVT defibrillator (Model A135). On or after June 17, 2005, Mr. Shreiner first

learned that the Guidant Vitality AVT defibrillator implanted in his body had an irregularity that could result in its failure to function. Mr. Shreiner has suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant Vitality AVT defibrillator, and knowledge that he might have, at any time, been fatally injured because of its malfunction. In addition, he was very concerned that he might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery.

23. Plaintiff Heather Sorensen is a citizen and resident of the State of California. Ms. Sorensen is represented by the law firms of Lieff, Cabraser, Heimann & Bernstein, LLP and Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC. Ms. Sorensen has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about August 31, 2001, Ms. Sorenson was implanted with a Guidant Ventak Prizm 2 DR ICD (Model 1861). Sometime around May, 2005, Ms. Sorensen learned that the Guidant Ventak Prizm 2 DR ICD implanted in her body had an irregularity that could result in its failure to function. Ms. Sorensen, who was pregnant at the time and the mother of two other young children, suffered extreme emotional distress as a result of the knowledge of the defective nature of her Guidant ICD, and knowledge that she might have, at any time, been fatally injured because of its malfunction. In addition, she was very concerned that she might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. Ms. Sorensen gave birth to her third child on July 11, 2005 by caesarean section surgery. On November 28, 2005, Ms. Sorensen's Guidant Ventak Prizm 2 DR ICD was replaced. Ms. Sorensen required additional surgery on February 28, 2006 to re-implant the defibrillator as its location had shifted. Ms. Sorensen suffered injuries and damages as a result of the explantation and adjustment surgeries.

24. Plaintiff Oren Urich is a citizen and resident of the State of Colorado. Mr. Urich is represented by the law firm of Burg, Simpson, Eldredge, Hersh & Jardine, P.C. Mr. Urich has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. On or about October 3, 2002, Mr. Urich was implanted with a Guidant Ventak Prizm 2 DR ICD (Model 1861). On or after June 17, 2005, Mr. Urich first learned that the Guidant Ventak Prizm 2 DR ICD implanted in his body had an irregularity that could result in its failure to function. Mr. Urich's physicians have determined that Mr. Urich's health is too frail to risk having his defibrillator replaced. As a result, Mr. Urich suffers extreme emotional distress as a result of the knowledge of the defective nature of his Guidant defibrillator, and knowledge that he might, at any time, be fatally injured because of its malfunction.

25. Plaintiff Edith Walker is a citizen and resident of the State of Oklahoma. Ms. Walker is represented by the law firms of Locks Law Firm, PLLC, Klafter & Olsen LLP, Heins Mills & Olson, and Lawrence E. Feldman & Associates. Ms. Walker has a severe cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. In late November 2002, Ms. Walker was implanted with a Guidant Ventak Prizm 2 DR ICD (Model 1861). Sometime after June 17, 2005, Ms. Walker learned that the Guidant Ventak Prizm 2 DR ICD implanted in her body had an irregularity that could result in its failure to function. Ms. Walker suffered extreme emotional distress as a result of the knowledge of the defective nature of her Guidant defibrillator, and knowledge that she might have, at any time, been fatally injured because of its malfunction. In addition, she was very concerned that she might get a life-threatening infection of the heart, endocarditis, as a result of the replacement surgery. In September 2005, Ms. Walker's Guidant Ventak Prizm 2 DR ICD was replaced. Ms. Walker suffered injuries and damages as a result of the explantation and surgery.

26. Individual and representative Plaintiff Larry Wenig is a citizen and resident of the State of New York. Mr. Wenig is represented by the law firms of Weitz & Luxenberg, P.C. and Seeger Weiss LLP. Mr. Wenig has a severe cardiovascular condition that requires the use of an implantable cardiac pacemaker/defibrillator. On or about June 29, 2001, Mr. Wenig was implanted with a Guidant Ventak Prizm 2 DR ICD (Model 1861). On or after May 24, 2005, Mr. Wenig first learned that the Guidant Ventak Prizm 2 DR ICD implanted in his body had an irregularity that could result in its failure to function. Mr. Wenig underwent a replacement of his Guidant ICD on August 3, 2005. Mr. Wenig suffered extreme emotional distress as a result of the knowledge of the defective nature of his Guidant ICD, and knowledge that he might have, at any time, been fatally injured because of its malfunction. In addition, Mr. Wenig suffered the pain of an unnecessary surgery and the anxiety that he could suffer from a life-threatening infection during or following surgery.

TPP Plaintiffs

27. Plaintiff UFCW Local 1776 and Participating Employers Health and Welfare Fund (hereinafter sometimes referred to as "UFCW Fund") is a citizen of the Commonwealth of Pennsylvania, and has its principal place of business at 3031B Walton Road, Plymouth Meeting, Montgomery County, Pennsylvania. UFCW Fund is represented by the law firms of Hagens Berman Sobol Shapiro LLP and Kenney Lennon & Egan. UFCW Fund is an "employee welfare benefit plan" and an "employee benefit plan" as defined in Employment Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1002(1), 1002(3), 1003(a). As such, UCFW Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). UCFW Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers, who are employed under

various collective bargaining agreements, and to their dependents. UCFW Fund has paid all or part of the cost of its participants' purchases, and associated medical expenses, of the Guidant products at issue in this litigation, as defined herein, including the medical expenses for the subrogee, John Doe. UCFW Fund has been injured as a result of the unlawful conduct of Defendants as alleged herein.

28. Plaintiff City of Bethlehem, Pennsylvania is self-insured in the area of group medical benefits for eligible employees. City of Bethlehem, Pennsylvania is represented by the law firms of Schiffrin & Barroway LLP and Head, Seifert and VanderWeide. At all times relevant hereto, said Plaintiff has been a party to a contract, issuer of a policy, or sponsor of a plan, where contract, policy, or plan provides medical coverage to natural persons. City of Bethlehem, Pennsylvania has incurred and will likely incur, pursuant to such contract, policy, or plan, full or partial costs for the Guidant products at issue in this litigation and related medical costs including implantation surgery, replacement cardiac devices, replacement surgery, medical monitoring, and/or other hospital costs. City of Bethlehem, Pennsylvania has been billed for and has paid charges for Guidant devices at issue in this litigation as described herein.

29. The TPPs seek several forms of relief. First, the TPPs seek class certification pursuant to Federal Rule of Civil Procedure 23(b)(2) and (b)(3), as well as interim appointments pending those class certifications under Rule 23(g). Second, the TPP claims seek non-monetary relief including disclosure (under appropriate protections for privacy) of the registrant list(s) maintained by Guidant to enable appropriate effectuation of the recall and the proper allocation of the economic burden of that recall. Third, the TPP claims seek monetary relief including payment for the wrongful economic burden placed on TPPs for the costs of replacement and/or corrective surgeries.

MSP Plaintiff

30. Plaintiff Tamela Ivens, at all times relevant herein, was and always has been a resident of the State of California. Ms. Ivens is represented by the law firms of Zimmerman Reed, PLLP and Jennings & Drakulich LLP. On January 14, 2004, Ms. Ivens was implanted with a Guidant Vitality AVT ICD (Model A155), which was developed, tested, marketed, warranted, and sold by Guidant. On or about August 5, 2005, Ms. Ivens had her Guidant Vitality AVT ICD surgically replaced with a non-Guidant ICD. Ms. Ivens is a Medicare beneficiary and serves for purposes of this Master Complaint as an exemplar and as a private attorney general under the Medicare Secondary Payor Act ("MSP"). Medicare has paid and is being charged for the medical expenditures resulting from the recalled ICD. Ms. Ivens also brings her own claims for personal injury.

Plaintiff Appearance In and Purpose Regarding the Master Complaint

31. All Plaintiffs, whether Device Recipient, TPP or MSP Plaintiffs, bring this action in their individual and/or representative capacities on their own behalf or on behalf of all others similarly situated in order to obtain the relief sought herein. The identity of the specific individuals who may be put forward as class representatives remains to be determined; where and when appropriate in the course of this litigation. Plaintiffs reserve the right to designate any additional class representatives at the appropriate time. The inclusion of a Plaintiff in this Master Complaint does not mean that such named Plaintiff will necessarily wish to be included in any class that may be proposed or certified. All Plaintiffs, whether named herein or who may hereafter file lawsuits and who may otherwise rely upon this Master Complaint, reserve the right to make their own determination regarding inclusion in any class at an appropriate time in these proceedings. Not all claims asserted in this Master Complaint will necessarily be held by, nor asserted by, all Plaintiffs.

32. This case is also brought by Plaintiffs as a public benefit action to deter Defendants and others similarly situated, in the future, from acting in any manner similar to the conduct described herein.

Defendants

33. Defendant Guidant Corp. is an Indiana corporation, with its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana. Guidant Corp. develops technology to treat conditions such as heart disease, neurological disorders, and vascular illness. Guidant's CRM Division is the division that develops, researches, advertises, promotes, markets, and sells all of Guidant's ICDs, some of which are marketed under the trade names Ventak Prizm, Contak Renewal, and Vitality. CRM Division's operations are principally conducted out of its facilities at 4100 Hamline Avenue North, St. Paul, Minnesota.

34. Guidant Corp. sells its ICDs and pacemakers through its wholly-owned subsidiary, Defendant Guidant Sales. Guidant Sales is an Indiana corporation, with its principal place of business at 111 Monument Circle in Indianapolis, Indiana.

35. Defendant CPI, a Minnesota corporation, developed Guidant's ICDs and pacemakers. CPI was merged into Guidant in or about September 1994, and is now a wholly-owned subsidiary of Guidant Corp., with headquarters at 4100 Hamline Ave. North, St. Paul, Minnesota.

36. Defendant Boston Scientific describes itself as a worldwide developer, manufacturer, and marketer of medical devices, whose products are used in a broad range of interventional medical specialties with reported revenue of $6.3 billion in 2005. Boston Scientific is incorporated in the State of Delaware with its principal executive office located in Natick, Massachusetts. In January 2006, Boston Scientific entered into an agreement to acquire Guidant

Corp. and its subsidiaries for approximately $27 billion. Pending final approval of that merger, which has been approved by Guidant 's stockholders, Boston Scientific is the successor in interest to Guidant and, directly or indirectly, has assumed Guidant's liabilities in this litigation.

JURISDICTION AND VENUE

37. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 as to the claims of individual Plaintiffs. The Court has jurisdiction under 28 U.S.C. § 1332(c) as to the class action claims because, among other things, this action includes parties and class members who are citizens of different states, who have claims in value of excess of $75,000 and, as to the class claims, the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs.

38. Venue is proper under 28 U.S.C. § 1391(a), (b) and (c), and 28 U.S.C. § 1407. Several Defendants maintain their principal place of business in this District; a substantial part of the events at issue in this litigation occurred in this District; Defendants maintain substantial facilities in this District; and Defendants earn compensation and profits from sales of their ICDs and pacemakers in this District. Venue for trial purposes is accordingly proper in this District.

FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

I. GUIDANT CORPORATE STRUCTURE

39. Guidant Corp. and its wholly-owned subsidiaries, Guidant Sales and CPI, design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. Guidant Corp.'s core biomedical businesses are divided into four divisions: Cardiac Rhythm Management, Cardiac Surgery, Endovascular Solutions, and Vascular Intervention.

40. Guidant Corp.'s products are sold through a combined sales organization, Guidant Sales.

41. Guidant Corp.'s business units present themselves under the "Guidant" corporate banner to the general public, including to the Food and Drug Administration ("FDA"), physicians, and individuals. As the Independent Panel that reviewed Guidant Corp.'s device surveillance and disclosure policies concluded, "the public views Guidant Corporation as a single entity, rather than a group of individual businesses." Independent Panel Report at 16. Guidant Corp. promotes such a view by, among other things, including the Guidant logo on all device marketing materials.

42. Guidant Corp.'s business units have their own officers but are also tied together at the corporate level by a structure by which Guidant Corp. oversees the business units, including through the Guidant Management Committee.

43. The products of Guidant Corp.'s CRM Division include ICDs, pacemakers, and lead systems. ICDs are implanted medical devices used to detect and treat abnormally fast and irregular heart rhythms, each of which can stop or hinder the heart from pumping blood effectively throughout the body and can result in sudden cardiac death. Pacemakers are medical devices used to detect and treat abnormally slow heart rhythms.

44. Guidant holds itself out as "the world leader in the design and development of cardiovascular medical products." Guidant Corp., Corporate Overview, http://www.Guidant.com/about_us.shtml (last visited April 11, 2006). ICDs have been Guidant Corp.'s fastest growing product for at least the last three years. The first ICD was placed on the market in 1985 by CPI, now wholly-owned by Guidant Corp. Between 2002 and 2004, Guidant Corp.'s revenues for sales of ICDs jumped 80% to $1.786 billion.

II. OVERVIEW OF IMPLANTABLE DEVICES FOR CARDIAC RHYTHM MANAGEMENT

45. Cardiovascular disease is the leading cause of death for both men and women in the United States. Implantable devices for cardiac rhythm management have become an integral part

of cardiovascular therapy. Implantable pacemakers for individuals with bradycardia (a slow heartbeat) were introduced more than 40 years ago, and the first ICD was implanted in 1980. (As used hereinafter, the term "Implantable Device" will refer to pacemakers and/or ICDs manufactured and sold by Defendants.) Thereafter, specialized pacemakers called cardiac resynchronization devices that improve the mechanical function of the heart were introduced and combined with existing ICD technology. Today, Implantable Devices are also commonly used for treatment of arrhythmia (an irregular heartbeat).

46. There has been explosive growth in ICD use. There are now, in just the United States, well over one million individuals living with an implanted cardiac rhythm device and this number is increasing rapidly. In 2005, approximately 200,000 people in the United States were implanted with ICDs.

47. The ICDs designed, manufactured and distributed into the stream of commerce by Guidant consist of three components: (1) a small rectangular generator, approximately two inches wide, which is implanted under the skin just below the collarbone; (2) insulated wires – or leads – which are attached to the generator and threaded through a vein to the heart, to carry the electric current from the generator; and (3) two electrodes, located at the tip of each lead, which deliver an electric shock to the heart.

48. The purpose of the ICD is to correct abnormal heart rhythm. The ICD can generate a series of precisely timed, low-intensity, electrical pulses to reset the heart to normal rhythm when the heart beats faster than normal (tachycardia); or the ICD can deliver sudden shocks to the heart to stop potentially fatal heart quivering (ventricular fibrillation). In addition, the ICD may be programmed as a pacemaker to send small electric signals if the heart beats too slowly (bradycardia).

49. Implantable CRT-D devices are medical devices that treat heart failure by helping the lower chamber (ventricles) pump synchronously with the upper chambers (atria), while preventing the heart from beating too slowly (bradycardia) and shocking or "over-drive pacing" of heartbeat rhythms that are too fast (a process by which the CRT-D is paced briefly at a rhythm faster than the desired rhythm in order to recapture control of the heartbeat).

50. All ICDs function as both pacemakers and defibrillators. The ICD can detect and correct both fast and slow heart rates. The ICD corrects the slow rates and can "over-drive pace" rapid rates and it also can administer shocks to treat ventricular tachycardia and ventricular fibrillation.

51. ICDs are used in individuals, like Plaintiffs, who have arrhythmias or irregular heartbeats that are considered life-threatening. These can include individuals with ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat) that is poorly controlled by medication, or significant thickening of the heart muscle resulting in arrhythmia. Such conditions can result in the loss of consciousness or death, unless the affected individual receives therapy from an appropriate device to put the heart back into a normal cardiac rhythm. Pacemakers are used in individuals, like Plaintiffs, who have bradycardia that is uncontrolled by medicine alone.

52. If an implanted ICD operates properly, it can save an individual's life. If it fails to operate properly, the individual could die within minutes.

53. Since 1958, pacemakers have been sold for implantation in individuals who have had certain spontaneous and/or inducible life-threatening arrhythmias, bradycardia, heart block, and congestive heart failure and those who are at high risk of developing bradycardia, heart block, or

arrhythmias. Pacemakers are used to manage disorders that disrupt the heart's normal electrical conduction system.

54. Pacemakers are designed to be implanted under the skin of the chest wall. The device's power source (pulse generator) is implanted in a pouch formed under the collarbone, just under the skin, usually on the upper left chest. Wires, called leads, are inserted through a blood vessel and attached directly into the heart. These wires, which are connected to the pacemaker or pulse generator, are capable of both sensing a problematic heart rate and stimulating a more appropriate heart rate.

55. Some individuals are very dependent on pacemakers to maintain an adequate heart rate, and therefore, cardiac output. For these individuals, failure of the cardiac pacemaker to provide pacing can cause sudden faintness, or loss of consciousness, and can result in death.

56. At all times relevant, Guidant misrepresented the safety of its ICDs and pacemakers and negligently manufactured, marketed, advertised, promoted, sold, and distributed those ICDs and pacemakers as safe devices to be used for treatment of individuals with prior myocardial infarction, arrhythmias, and individuals who are at high risk for developing such arrhythmias.

III. DEVICES AT ISSUE

57. As detailed below, this Master Complaint seeks recovery for individuals who have been implanted with certain Guidant ICDs and pacemakers, hereafter collectively referred to as the "Devices."

58. This Master Complaint seeks recovery for individuals who have been implanted with ICDs marketed by Guidant under the following model names:

(i) Ventak Prizm 2 DR Model 1861 (hereinafter "Ventak Prizm 2 DR 1861");

(ii) the Contak Renewal 1 Model H135 (also known as the Contak Renewal H135) and Contak Renewal 2 Model H155 (also known as the Contak Renewal H155);

(iii) the Contak Renewal 3, Contak Renewal 4, Renewal 3 AVT, Renewal 4 AVT, and Renewal RF implantable CRT-Ds; and

(iv) the implantable atrial therapy devices called Ventak Prizm AVT, Vitality AVT, Renewal RF, and Renewal AVT (hereinafter "AVTs").

59. This Master Complaint seeks recovery for individuals who have been implanted with pacemakers marketed by Guidant under the following model names (hereafter collectively referred to as the "Pacemakers"):

(i) Pulsar Max, Models 1180, 1171, and 1280;

(ii) Pulsar, Models 0470, 0870, 0970, 0972, 1172, and 1272;

(iii) Discovery, Models 1174, 1175, 1273, 1274, and 1275;

(iv) Meridian, Models 0476, 0976, 1176, and 1276;

(v) Pulsar Max II, Models 1170, 1171, 1270;

(vi) Discovery II, Models 0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, and 1286;

(vii) Virtus Plus II, Models 1380 and 1480 ;

(viii) Intelis II, Models 1483,1484, 1485, 1384, 1385, 1349, and 1499;

(ix) Contak TR, Model 1241; and

(x) Insignia and Nexus models.

60. As part of the conditions of approval for the Devices, Defendants must ensure that no changes be made to the Device that would affect its safety or effectiveness without submission of a Pre-Market Approval ("PMA") supplement for review and approval, and that a PMA

supplement must be submitted when a device failure necessitates a labeling, manufacturing, or device modification. Violation of such conditions voids their approval.

61. The removal of Devices from the market and other corrective actions taken by Guidant have been classified as Class I or Class II recalls under federal regulations – the highest levels of such recalls.

62. Under federal regulation "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. § 7.3(g) (2006).

63. The classification of a recall as Class I, II, or III "indicate[s] the relative degree of health hazard presented by the product being recalled." *Id.* § 7.3(m). "Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." *Id.* § 7.3 (m)(1). "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." *Id.* § 7.3 (m)(2).

64. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal requlations. *See* 21 U.S.C. § 351 (2006).

65. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

66. Manufacturers are required to comply with FDA regulation of medical devices, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360i.

67. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. § 803.50.

68. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. § 803.52.

69. Manufacturers must report to the FDA in five business days after becoming aware of any reportable medical device reporting ("MDR"). MDR events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. *See* 21 C.F.R. § 803.53

70. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. § 806.10.

71. Manufacturers must comply with quality system regulations that require manufacturers to meet design-control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming product and take corrective action to prevent recurrence. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is

necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See generally* 21 C.F.R. § 820.

72. A manufacturer must report to the FDA through a PMA supplement any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device. A manufacturer may implement changes to a device that enhance the safety of the device prior to obtaining FDA approval, if the manufacturer submits a special report entitled: "Special PMA Supplement - Changes Being Effected" and provides a full explanation of any labeling changes or changes in quality control or manufacturing process that add a new specification of test method, or otherwise provide additional assurance of purity, strength, or reliability of the device.

73. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." Conditions of Approval at 1, attached to FDA Approval Letter from Daniel G. Schultz, Deputy Director for Clinical Policy, FDA, to Kaye Anderson, Senior U.S. Regulatory Affairs Associate, Guidant Corporation (July 18, 2002); *see* 21 C.F.R. § 814.39.

74. Guidant's failure to meet federal regulations applicable to medical devices and Guidant's other acts and omissions as described herein directly and proximately caused the Devices to be in violation of federal law and unfit for sale, and proximately caused harm, injury, and deaths to Plaintiffs and their decedents. Plaintiffs' state law claims are based on parallel state law provisions that do not conflict with federal law.

IV. HISTORY OF THE DEVICES

A. Summary

75. Guidant manufactured, promoted, sold, and distributed each of the Devices.

76. At all relevant times, Guidant misrepresented the safety of the Devices and negligently manufactured, sold, promoted and distributed them as safe and effective Devices to be used for treatment of individuals with cardiac issues.

77. While Guidant was aware that any of the Devices might be subject to certain random and infrequent failures, Guidant was also aware of specific, potentially fatal, and nonrandom failures that would occur in the Devices.

78. In March 2005, the death Joshua Oukrop, whose Ventak Prizm 2 DR 1861 failed, prompted an inquiry first by his physicians. According to a May 24, 2005, New York Times article, the doctors who treated Mr. Oukrop felt that Guidant should have notified physicians of the defective nature of the device, since the company "had received enough reports about the flaw to establish a pattern and because high-risk individuals could suffer potentially catastrophic results," such as those that befell Mr. Oukrop. Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. Times, May 24, 2006, at A. Faced with Guidant's refusal to disclose to the medical community or the public the potentially fatal defects that their investigation uncovered, Mr. Oukrop's physicians brought the issues to the attention of the New York Times.

79. The New York Times' disclosure that Guidant had known of defects in the Ventak Prizm 2 DR 1861 attracted a great deal of attention. As further information was revealed, it became apparent that Guidant's CRM Division had known for more than three years that there were defects in the Ventak Prizm 2 DR 1861 and that Guidant had been aware of defects in other Devices.

80. Since May 2005, Guidant has issued at least 35 notices, in the form of "Dear Doctor" and "Dear Patient" letters, voluntary recalls, and medical advisories relating to the Devices. Even then, some of the advisories and information provided by Guidant has been inconsistent, unclear and incomplete. On at least one occasion, a Guidant suggestion was subsequently revoked by another Guidant advisory. As a consequence, and as described below, today recipients and their medical advisories remain confused and unclear as to the risks of the Devices and the appropriate course of action to take.

81. Certainly, prior to 2005 and despite knowledge of defects in the Devices, Guidant failed to communicate information about the defects to the medical community, individuals who had been implanted with the Devices, or the public.

82. While Guidant had provided some information to the FDA, that information was incomplete and misleading and did not adequately disclose the Device defects. Guidant's flawed disclosures did not comply with FDA regulations and violated the conditions of approval for the Devices.

83. As a result of manufacturing defects, the Devices are unfit for the purpose for which they were sold and do not function as Guidant had represented to the FDA, the medical community, and the public. The Devices, in fact, may lead to serious physical trauma and/or death. Guidant knew and had reason to know of this tendency for malfunction, device failures, and the resulting risk of injury and death; and yet Guidant concealed, omitted, and suppressed this material information, preventing Plaintiffs, the medical community, regulators, and the public from making informed choices about the use of the Devices.

B. Ventak Prizm ICDs

84. Guidant designed, manufactured, marketed, promoted, sold, and distributed twelve models of defective pacemaker/defibrillator combinations in the Ventak Prizm line of devices,

including the Ventak Prizm 2 VR/DR, Models 1860/1861, Ventak Prizm VR/DR, Models 1850/1851/1855/1856, the Ventak Prizm DR HE, Models 1852/1853, the Ventak Mini IV, Models 1790/1793/1796, and Ventak Mini III HE, Model 1789 (collectively, these are referred to as "Ventak Prizm ICDs").

85. The Ventak Prizm 2 DR 1861 has a potentially fatal defect that can cause short circuiting due to deterioration of a wire insulator within the lead connector block, or header, of the device. The short circuit prevents the Ventak Prizm 2 DR 1861 from providing the necessary and appropriate therapeutical shocks to correct a heart rhythm.

86. Guidant first submitted Ventak Prizm for approval in August 1996 pursuant to PMA P960040. The device was originally approved for sale by Guidant on July 18, 1997. The original approved device was Ventak Prizm (Models 1810 and 1815). On January 27, 1999, Guidant announced the first implantation of the Ventak Prizm.

87. Pursuant to PMA Supplement P960040 S015, Guidant sought approval of Ventak Prizm 2 VR/DR (Models 1860 and 1861). Guidant received notice of approval of this PMA Supplement in August 2000. Guidant began selling the Ventak Prizm 2 DR 1861 in 2000.

88. On July 18, 2002, under supplemental approval, the FDA expanded the approved indication of all the Ventak Prizm ICDs for the prophylactic treatment of individuals with prior myocardial infarctions and an ejection fraction of 30% or more.

89. According to Guidant's May 25, 2005 press release, approximately 24,000 Ventak Prizm 2 DR 1861 ICDs are currently implanted in individuals worldwide. *See* Press Release, Guidant Corp., *Guidant Notifies Physicians Regarding Ventak 1861 Prizm 2 DR Implantable Defibrillator* (May 25, 2005) ("May 25 Guidant Press Release"). Guidant later informed the New

York Times that as many as 37,000 defective Ventak Prizm 2 DR 1861 devices were implanted. *See* Barry Meier, *Flawed Implants: Disclosure and Delay*, N.Y. Times, June 14, 2005, at C.

90. Guidant's Ventak Prizm 2 DR 1861s manufactured are uniformly defective in that they suffer a deterioration of electrical insulation, which will eventually cause the devices to short circuit and fail to function. The malfunction also erases the device's memory, such that a record of the malfunction and any of the patient's previous cardiac arrhythmias is no longer stored in the device, making care provisions for the individuals that much more difficult.

91. At present Guidant has not disclosed any test that can predict whether the device will fail, and the device itself gives no warning before or during the malfunction. The defect can be readily detected only in the rare event that the ICD happens to be tested by an electrophysiologist during a short period of time during malfunction. It is not yet clear how often individuals will have to be examined to determine whether their ICD has short circuited and it remains unclear, from what has been made available to the public, as to whether there is an alternative method of identifying a defective device that would minimize the need for ongoing constant examination and medical surveillance. In many cases, the short circuiting erases the device's memory of any adverse event so that the usual telemetric surveillance is not useful.

92. Explantation of the device also has risks, as the ICD is linked directly to the heart, with a lead wire connection placed into the heart tissue. In this situation, scarring occurs easily.

93. In or before February 2002, Guidant learned that Ventak Prizm 2 DR 1861s were short circuiting when attempting to build a charge to deliver a therapeutic shock. Specifically, Guidant knew that electricity could arc between a lead wire and the backfill tube in the Ventak Prizm 2 DR 1861.

94. By May or June 2002, Guidant's observation of the pattern of short circuiting in the Ventak Prizm 2 DR 1861 was sufficient for a Guidant Product Performance Engineer to classify the problem as a "trend" that required further investigation.

95. Meanwhile, by April 2002, Guidant had determined that a manufacturing change should be implemented to attempt to adjust the potentially fatal defect in the Ventak Prizm 2 DR 1861. Without FDA approval or any contemporaneous disclosure to the FDA, the medical community, or the public, Guidant modified the manufacturing specifications and process of the Ventak Prizm 2 DR 1861 to increase the spacing between the feedthru wire and the backfill tube through injection of additional medical adhesive into the device.

96. In November 2002, once again without FDA approval or any contemporaneous disclosure to the FDA, the medical community, or the public, Guidant made further modifications to the manufacturing specifications and process of the Ventak Prizm 2 DR 1961 to thicken the insulation on the backfill tube.

97. Even after April 2002, however, Guidant continued to sell the remaining defective ICDs it had in its inventory stock without any disclosure regarding the potentially fatal defect. According to the Independent Panel Report that investigated Guidant's practices with respect to reporting device defects, Guidant allowed 4,000 such devices to be sold for implant after knowledge of the defect, 1,300 of which Guidant shipped after knowledge of the defects. The Independent Panel concluded that, despite knowledge of the defect, Guidant made no effort to retrieve defective devices in medical institutions' inventories and that subsequent manufacturing changes were not brought to the attention of physicians or patients.

98. A June 2, 2005 New York Times article revealed that after April 2002, and after Guidant had clear and definite knowledge of the defect, nine defective ICDs (manufactured before

April 2002 and therefore lacking the modifications intended to increase the spacing between the feedthru wire and the backfill tube) were implanted in individuals at Abbott Northwestern Hospital alone. According to a May 24, 2005 New York Times article, in three cases, the Ventak Prizm devices failed to work when doctors intentionally induced abnormal heart rhythms during checkups, forcing the doctors to rescue the individuals with external defibrillator paddles of the type used in emergency rooms.

99. In April 2003, Guidant closed out the "trend report" on the Ventak Prizm 2 DR 1861, with full knowledge that thousands of those devices that were manufactured before Guidant's changes were still implanted and prone to failure.

100. After April 2002, Guidant received further information regarding continued failures in the Ventak Prizm 2 DR 1861. For example, Guidant received reports of short circuiting in February and July 2004. By February 2005, at least 25 events related to the known problem in the Ventak Prizm 2 DR 1861 had been reported to Guidant.

101. On March 14, 2005, a 21-year-old college student from Minnesota with hypertrophic cardiomyopathy collapsed and died of sudden cardiac death when his Ventak Prizm 2 DR 1861 failed due to an electrical short circuit.

102. Physicians at the Minneapolis Heart Institute Foundation explanted the failed device and sent it to Guidant for analysis. Guidant's analysis confirmed that the device (i) short circuited internally, (ii) had been permanently disabled and (iii) had its memory destroyed. As a result, the device failed to deliver the electric shock necessary to correct the young man's heart rhythm, causing his death.

103. Physicians at the Minneapolis Heart Institute Foundation searched the FDA database for adverse events involving medical devices and identified several other reports involving the

Ventak Prizm 2 DR 1861, where the device short circuited and failed in the same manner as their patient's device. They then confronted Guidant officials on May 12, 2005 regarding the recurring electrical short-circuiting defect they had discovered in the Ventak Prizm 2 DR 1861 and reminded Guidant of its obligations to notify patients and physicians of the defect. Guidant officials, however, refused and maintained instead that there was no reason to notify physicians, patients, or the public of the defect in their product.

104. Guidant made no public disclosure of the defect in the Ventak Prizm 2 DR 1861 until May 23, 2005, more than three years after Guidant learned of the defect, and just hours before the New York Times published an article disclosing the details of the Minnesota young man's death.

105. While Guidant officials took no action to warn the public of the defects in its device prior to May 23, 2005, at least one Guidant official did act in the interim to sell company stock. On May 17, 2005, Guidant's Chief Medical and Technology Officer sold 23,300 shares of stock in the company for $1.71 million, and on May 23, 2005, the day before the front-page article in the New York Times, she sold another 22,667 shares for $1.68 million.

106. On June 17, 2005, Guidant informed physicians in a Dear Doctor letter that it had received twenty-eight reports of the short-circuiting failure in the Ventak Prizm 2 DR 1861s manufactured prior to April of 2002, including one death related to failure of the device, and issued a nationwide notification of recall of the device. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Ventak Prizm® 2 DR, Model 1861 (June 17, 2005) ("June 17 Dear Doctor Letter").

107. In the June 17, 2005 Dear Doctor Letter, Guidant described the malfunction as follows: "[D]eterioration in a wire insulator within the lead connector block, in conjunction with

other factors, result[s] in an electrical short. The short caused diversion of shock therapy energy away from the heart and into device circuitry. Resultant circuit damages caused permanent loss of shock therapy and pacing." *Id.* at 1.

108. Guidant did not file the required PMA Supplement with respect to the 2002 manufacturing changes to the Ventak Prizm 2 DR 1861. Although Guidant filed a nonpublic annual report with the FDA in August 2003, Guidant's disclosure did not reveal that the Ventak Prizm 2 DR 1861 ICDs might be subject to a potentially fatal failure or that Guidant's disclosure was incomplete, misleading, and improper, and was intended to hide the known defect in existing Ventak Prizm 1861s from Plaintiffs and others who were implanted with the device.

109. Guidant knew, as well, that the substance used to insulate the wires – polyimide – was prone to failure. Guidant became aware that polyimide was specifically prone to cracking which, when combined with exposure to bodily fluids, could lead to potentially fatal short circuiting in the Ventak Prizm 2 DR 1861. Thus, Guidant determined that it would replace the polyimide tubing with another substance, PEEK.

110. Finally, after public disclosures of Guidant's misconduct, on June or July of 2005, Guidant applied for FDA approval to replace polyimide with PEEK in certain devices, such as the Ventak Prizm 2 DR 1861. The FDA approved this change in August 2005 and, in October 2005, described it as "replacing the insulating material on the feedthru wires with a different material that has better degradation properties." FDA, Update of FDA Preliminary Public Health Notification*: Guidant Ventak Prizm 2 DR and Contak Renewal Implantable Cardioverter Defibrillators at 1 (Oct. 13, 2005).

111. In Guidant's May 23, 2005, communication with doctors, it did not recommend replacement of the Ventak Prizm devices. *See* May 25, 2005 Guidant Press Release. Moreover,

reports suggest that Guidant's sales representatives continued to assure physicians that it was unnecessary to replace the defective devices in their individuals.

112. To this day, Guidant refuses to suggest replacement of the defective Ventak Prizm 2 DR 1861 devices. Despite patient deaths as a result of the malfunction, and despite Guidant's admission that the actual rate of failures may be greater than the reported rate (because deaths associated with device failures may be under-reported because the devices are not routinely evaluated post mortem), Guidant told physicians to continue "normal monitoring" and did not encourage them to explant the devices. More recently (and contrary to Guidant's original advice to patients and physicians), Guidant has recommended that a commanded, or induced, shock may be performed to confirm the integrity of circuitry for individuals implanted with a Ventak Prizm 2 DR 1861, although such testing will not exclude the likelihood the device might later fail because of the defect.

113. Nevertheless, the FDA has classified the actions taken by Guidant with regard to the Ventak Prizm 2 DR 1861 devices as Class I recalls, meaning there is "a reasonable probability" that the malfunctioning device "will cause serious adverse health consequences or death." FDA News, FDA Updates Consumers on Guidant Corporation's Implantable Defibrillators (July 1, 2005) ("July 1 FDA Press Release"). The "recalls require Guidant to disclose the device malfunction to patients and doctors while providing additional instructions for safe use of the devices." *Id*.

114. As of December 2005, the FDA reported that two deaths had been linked to the Ventak Prizm 2 DR 1861. While Guidant reported a predicted occurrence rate of 0.10% to 0.24% in Ventak Prizm DR 1861 devices that were manufactured on or before April 16, 2002, it stated that its computations of potential occurrence rate could be artificially low and that its predictive

modeling is "inherently uncertain." Guidant also disclosed that a failure had been associated with a Ventak Prizm 2 DR 1861 that was manufactured after April 16, 2002.

115. At all times relevant to this action, Guidant knew, and had reason to know, that the Ventak Prizm 2 DR 1861 was not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

C. Contak Renewal 1 and 2

116. Guidant manufactured CRT-Ds known as Contak Renewal Model H135 and Contak Renewal 2 Model H155 (hereinafter collectively "Contak Renewal 1 & 2").

117. In or before November 2003, Guidant became aware that the Contak Renewal 1 & 2 were prone to short-circuiting problems similar to those found in the Ventak Prizm 2 DR 1861. Like the Ventak Prizm 2 DR 1861, the Contak Renewal 1 & 2 included polyimide tubing.

118. From November 2003 to May 2005, Guidant knew of multiple instances in which Contak Renewal 1 & 2 devices had short circuited, including that the short circuiting had resulted in at least one death.

119. While Guidant knew that the Contak Renewal 1 & 2 were defective, it failed to disclose the defect to the FDA, the medical community, and the public and continued to sell Contak Renewal 1 & 2 devices with the defect. Not until September 2004 did Guidant consider stopping the sale of the defective Contak Renewal 1 & 2 devices, and even then, determined that the Guidant sales staff should misrepresent to the medical community the reason for any resulting inventory backorders, in order to avoid questions that could lead to explanation of existing defective devices.

120. In January 2005, Guidant considered withdrawing Contak Renewal 1 & 2 devices from the market because of the defects, but concluded that Guidant would not disclose the Contak Renewal 1 & 2 defect or withdraw the devices from the market because of the number of defective devices that would be implanted by the time of any such action.

121. On June 17, 2005, only after Guidant had been forced to disclose the Ventak Prizm 2 DR 1861 defect and the FDA had initiated a review of Guidant's other Devices, did Guidant issue a letter to doctors disclosing the defective nature of the Contak Renewal 1 & 2. Specifically, as to these devices, Guidant stated that its laboratory analysis had proven that the Contak Renewal 1 & 2 had failed due to "deterioration in a wire insulator within the lead connector block [which,] in conjunction with other factors, could cause a short circuit and loss of device function due to diversion of therapy energy away from the heart and into device circuitry." Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Contak Renewal Model H135 and Contak Renewal 2 Model H155 Devices Manufactured on or Before August 26, 2004 at 1 (June 17, 2005) ("June 17 Contak Renewal 1 & 2 Letter").

122. Guidant stated that there is no way of predicting whether "any particular device will fail." *Id.* at 3. According to the June 17 Contak Renewal 1 & 2 Letter, fifteen reports of the malfunction had been confirmed, at least, one of which was fatal, and approximately 16,000 of the devices had been implanted worldwide. *See id.* at 1.

123. Since the June 17 Contak Renewal 1 & 2 Letter, more reports of the malfunction have been confirmed by Guidant and at least three more deaths have been associated with the Contak Renewal 1 & 2 defect.

124. Guidant further advised physicians to consider performing a commanded shock of the ICD to confirm the integrity of the high-voltage delivery system, and warned physicians that Devices that had failed should be explanted and replaced with new Devices.

125. Guidant also stated that, in regard to the Contak Renewal 1 & 2, it had "implemented design and manufacturing corrective actions to address internal shorting within the device header. No devices manufactured after August 26, 2004 have exhibited this failure." *Id.* at 3.

126. Once again, despite the fact that Guidant made manufacturing changes on or around August 26, 2004, which it represented had corrected the defect in the Contak Renewal 1 & 2 devices, Guidant failed to inform physicians, patients, and the public until the June 17 Contak Renewal 1 & 2 Letter.

127. In June 2005, Guidant recommended that physicians assess whether to replace the Contak Renewal 1 & 2 devices. In September 2005, Guidant recommended that physicians reassess device replacement "as a result of the increased projected rate of occurrence." Guidant Corp., Advisory Update: Contak Renewal and Contak Renewal 2, Models H135 and H155 (Sept. 12, 2005).

128. Guidant has stated that its estimation of the level of device malfunction in the Contak Renewal 1 & 2 is likely to be understated because the actual number of clinical failures may be greater than the number reported and its predictive modeling is inherently uncertain.

129. The FDA has classified the action taken by Guidant with regard to the Contak Renewal 1 & 2 as a Class I recall. The recall requires Guidant to disclose the device malfunction to individuals and doctors while providing additional instructions for safe use of the devices.

130. Meanwhile, as with the Ventak Prizm 2 DR 1861, Guidant had concluded that the polyimide insulation tubing used in the Contak Renewal 1 & 2 was susceptible to cracking that could result in short circuiting of the device.

131. As with the Ventak Prizm 2 DR 1861, each failure of a Contak Renewal 1 & 2 is potentially fatal.

132. In December 2005, the FDA reported that there had been at least five deaths associated with the defect in the Contak Renewal 1 & 2 and that additional clinical occurrences are likely.

133. At all times relevant to this action, Guidant knew, and had reason to know, that the Contak Renewal 1 & 2 were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

D. Contak Renewal 3 and 4

134. Guidant also manufactured Contak Renewal 3, Contak Renewal 3 HE, Contak Renewal 4, Contak Renewal 4 HE, Contak Renewal 3 AVT, Contak Renewal 3 AVT HE, Contak Renewal 4 AVT, Contak Renewal 4 AVT HE, Renewal RF, and Renewal RF HE CRT-Ds (hereafter referred to as "Contak Renewal 3 & 4").

135. Long before June 2005, Guidant knew that Contak Renewal 3 & 4 were subject to a component failure, in which a magnetic switch can become stuck in the closed position, interfering with the device's ability to treat tachyarrhythmias and depleting the battery. This failure can negatively affect the functioning of the Contak Renewal 3 & 4 devices.

136. Guidant has recommended that physicians cease implantation of the Contak Renewal 3 & 4 and use a different product that contains a new switch component. As to currently implanted Contak Renewal 3 & 4 devices, Guidant has recommended that individuals seek medical intervention to switch the magnet off and seek immediate medical attention if the device is emitting audible tones. In June 2005, Guidant promised, but has not delivered as of it latest Product Performance Report issued in 2006, a programmer software application to correct the problem. The FDA has classified Guidant's actions with respect to Contak Renewal 3 & 4 as a Class II recall, which is defined as a product malfunction that may cause temporary or medically reversible adverse heath consequences.

137. At all times relevant to this action, Guidant knew, and had reason to know, that the Contak Renewal 3 & 4 were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and potentially catastrophic injuries and deaths.

E. Ventak Prizm AVT, Vitality AVT, and Renewal AVT

138. Guidant manufactured potentially defective implantable atrial therapy devices called Ventak Prizm AVT, Vitality AVT and Renewal AVT (collectively referred to as "AVTs"). The Renewal AVT 3 and 4 devices are also subject to the same magnetic switch failure as the Contak Renewal 3 & 4 devices.

139. On or before May 2002, Guidant knew that the AVTs were subject to a condition in which a random memory error causes functional "latching" that limits available therapy. A "latched" AVT can also enter a mode of continuous pacing at 120 beats per minute.

140. When an AVT is "latching," it is unable to detect and treat arrhythmias and will fail to recognize and correct a cardiac rhythm that is too fast or irregular, potentially leading to injury or

death. Other effects of AVT "latching" include decreased cardiac output, increased myocardial oxygen demand, and excessive wear on the device's battery. If the latching occurs during AVT therapy (i.e., while the AVT is attempting to deliver a shock), continuous shocks could result, regardless of whether they are medically appropriate or necessary. Guidant developed and implemented a "fix" to correct the latching in May 2004, but did not disclose to the FDA that the "fix" would be implemented in manufacturing the AVTs until August 2005, after the exposure of the Ventak Prizm 2 DR 1861 defects. Not until June 17, 2005 did Guidant notify doctors or the public that device replacement was required if latching occurs and that the issue could be corrected if an implanted AVT – that had not latched – was reprogrammed.

141. On or around July 22, 2005, Guidant informed doctors and the public that the programming change recommended in June 2005 could actually cause latching to occur in the AVTs and suggested that a "non-invasive software solution" would be available around September 2005. Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Ventak Prizm AVT, Vitality AVT, and Contak Renewal AVT (July 22, 2005).

142. In January 2006, Guidant noted that thirty more failures had been identified, several of which appeared to be related to Guidant's improper programming notification. As of April 2006, Guidant has not issued the "non-invasive software solution."

143. Individuals implanted with AVT devices must undergo medical monitoring to determine whether their device is functioning properly. In the event Guidant issues a "software solution," individuals implanted with AVT devices will require additional medical attention to implement the solution.

144. The FDA originally classified Guidant's actions with regard to the AVT devices as a Class II recall. However, after Guidant incorrectly advised the medical community of a

programming change that would actually increase the likelihood that latching would occur, the FDA converted Guidant's actions with regard to the AVT devices to a Class I recall. According to the FDA, approximately 21,000 of the devices have been implanted worldwide.

145. At all times relevant to this action, Guidant knew, and had reason to know, that the AVTs were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

F. Discovery, Pulsar, Meridian, Virtus, and Intelis Pacemakers

146. Guidant manufactures a family of pacemakers that includes the Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II, Discovery II, Contak TR, Virtus Plus II, and Intelis II devices (hereafter referred to as "Guidant Pacemakers").

147. As a result of defects in manufacturing, Guidant Pacemakers are subject to degradation of a hermetic sealing component. The result is excessive moisture in the pacemaker case, leading to premature battery depletion and failures to function properly.

148. The failures in the Guidant Pacemakers can occur without warning although, sometimes, a physician can detect a leak-related malfunction before the malfunction causes serious problems.

149. Although Guidant knew of the problems with the Guidant Pacemakers as early as 2004, yet again, Guidant did not disclose the problems to the FDA, the medical community, or the public until almost two months after the adverse press regarding the hidden defect in the Ventak Prizm 2 DR 1861.

150. Guidant first disclosed the problem with degradation of the hermetic sealing component in a letter to doctors on July 18, 2005. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II,

Discovery II, Virtus Plus II, Intelis II, and Contak TR Devices at 1 (July 18, 2005) ("July 18 Dear Doctor Letter"). According to Guidant, the leakage into the pacemaker seal can lead to premature battery depletion ("resulting in loss of telemetry and/or loss of pacing output without warning") and inappropriate accelerometer function (resulting in sustained pacing at the maximum rate and lack of appropriate accelerometer rate response during activity). *Id.*

151. The defective Guidant Pacemakers are potentially life-threatening. Loss of pacing output can cause individuals to experience syncope, sometimes requiring hospitalization, and can cause death. Sustained maximum rate pacing has caused heart failure in some individuals implanted with the Guidant Pacemakers, by increasing myocardial oxygen demand. In at least one case, a patient whose device exhibited sustained maximum rate pacing was admitted to the hospital with multiple health issues and subsequently died.

152. According to Guidant, testing can determine which devices have already experienced failure, but there is no test to determine if and when devices will fail in the future. Guidant estimates that any of the 18,000 Guidant Pacemakers still implanted in residents of the United States may potentially be affected by the hermetic seal degradation defect.

153. In its July 18, 2005 Dear Doctor Letter, Guidant advised doctors to consider replacing the affected Guidant Pacemakers in individuals who depend on the device for survival or to prevent serious health consequences. *See id* at 2. According to two cardiologists interviewed for the New York Times, between 20% to 40% of individuals with pacemakers are dependent on their pacemaker for survival. *See* Barry Meier, *Pacemakers By Guidant Have Flaw*, N.Y. Times, July 19, 2005.

154. Guidant also advised that individuals should seek attention immediately, "if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new or increased symptoms of heart failure." July 18 Dear Doctor Letter at 2.

155. The explanation recommended by Guidant to address the defects in the Guidant Pacemakers will subject thousands of individuals to explantation surgery and related risks and trauma.

156. Guidant has also recommended that individuals implanted with the Guidant Pacemakers consider increasing the frequency of medical visits to increase the likelihood of detecting a failure that has already occurred.

157. The FDA has classified Guidant's action with respect to the Guidant Pacemakers as a Class I recall.

158. Since July 2005, Guidant has issued further advisories about potential hermetic seal degradation in the Guidant Pacemakers. Specifically, on January 23, 2006, Guidant announced that the Guidant Pacemakers may also be subject to hermetic seal degradation because of a manufacturing error, in which hermetic sealing components susceptible to gradual degradation were mistakenly mixed with a much larger group of non-susceptible components. Guidant stated that there is no way to determine which of the 54,000 potentially affected devices might be defective due to the use of improper materials.

159. At all times relevant to this action, Guidant knew, and had reason to know, that the Guidant Pacemakers were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

G. Insignia and Nexus Pacemakers

160. On or before March 2004, Guidant knew that various models in its Insignia and Nexus line of pacemakers ("Insignia & Nexus") are subject to two failure modes.

161. Guidant did not disclose the failure modes to the medical community or the public although, by September 1, 2005, Guidant had knowledge of at least forty-nine device failures related to the Insignia & Nexus defects.

162. Until the FDA's inspection of Guidant's facilities, Guidant also failed to fully disclose the Insignia & Nexus defects to the FDA. Guidant's disclosure of the Insignia & Nexus device failures was required based on FDA's discovery of the defects and conclusions that Guidant had violated numerous federal regulations in manufacturing the Insignia & Nexus devices and in failing to investigate properly and disclose those defects.

163. In the first failure mode, which Guidant first disclosed on September 22, 2005, up to 49,500 Insignia & Nexus devices may be subject to failure due to "foreign material within a crystal timing component." Guidant Corp., Important Medical Device Safety Information & Corrective Action at 1 (Sept. 22, 2005). According to Guidant, the foreign material was eliminated in Insignia & Nexus devices shipped after March 12, 2004. *See id.*

164. In the second failure mode, which Guidant first disclosed on September 22, 2005, up to 341,000 Insignia & Nexus devices may exhibit a failure of pacing for which Guidant could not determine the cause. *See id.* at 2. While Guidant asserted that this defect had only been noted at implant, at least one individual had experienced cardiac arrest during attempted implant of a defective Insignia & Nexus device.

165. Guidant was unable to identify which Insignia & Nexus devices would fail and suggested medical treatment for individuals feeling short of breath, dizzy, or lightheaded. For the

second Insignia & Nexus failure mode, Guidant suggested verifying the pacing output of the device before implantation.

166. The FDA has classified Guidant's actions with respect to the Insignia & Nexus devices as Class II recalls. A Class II recall is defined as a product malfunction that may cause temporary or medically reversible adverse health consequences.

167. At all times relevant to this action, Guidant knew, and had reason to know, that the Insignia & Nexus devices were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, potentially causing catastrophic injuries and deaths.

H. Pending Recalls

168. Guidant has continued to issue advisories regarding its cardiac Devices. Guidant's latest advisory, on March 11, 2006, stated that Contak Renewal 3 RF and Contak Renewal 4 RF devices may exhibit a decline in battery voltage related to an unexpected sustained, low level current. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Guidant Renewal 3 RF & Renewal 4 RF (CRT-Ds) at 1 (Mar. 11, 2006). Although Guidant claims that the defect can only occur during storage/shipment mode prior to implant, Guidant also states that it has confirmed that the internal low level current may occur "transiently" in normal use post implant.

169. Guidant has advised that the FDA may classify this communication regarding the Contak Renewal 3 RF and Contak Renewal 4 RF as a recall.

V. GUIDANT'S PAST AND PRESENT ILLEGAL AND REPREHENSIBLE CONDUCT

A. Guidant's Failure To Meet Basic Manufacturing & Regulatory Standards

170. The FDA conducted an inspection of Guidant's facilities during the time period of August 22, 2005 to September 1, 2005. At the conclusion of the inspection, the FDA issued a 483 Inspection Report ("FDA 483"), in which it detailed violations of federal regulations by Guidant. *See* FDA 483 Inspection Report (Sept. 1, 2005) ("Sept. 1 FDA 483").

171. The stated purpose of the FDA 483 is "to assist the firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration." FDA 483 Inspection Report at 2 (Feb. 8, 2006) ("Feb. 8 FDA 483").

172. Included in the Sept. 1 FDA 483 for Guidant were the following fifteen observations of violations noted by FDA:

(1) procedures for conducting quality audits were incomplete;

(2) "[n]ot all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified;"

(3) procedures were not completed and implemented for monitoring and controlling of process parameters for validated processes;

(4) "[a] process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures;"

(5) "[p]rocedures to ensure that equipment is routinely maintained were not established;"

(6) "[d]uring production, component and device characteristics are not fully monitored and controlled;"

(7) "[p]rocedures for changes to methods were not complete;"

(8) management with executive responsibility has not ensured that an adequate and effective quality system has been implemented and maintained at all levels of the organization;

(9) "[s]oftware used as part of production and the quality system has not been fully validated for its intended use according to an established protocol," and electronic records which are used do not have requirements to ensure that they are trustworthy, reliable, and generally equivalent to paper records;

(10) "appropriate sources of quality data are not adequately analyzed to identify existing and potential causes of nonconforming product and other quality problems;"

(11) processes have not been approved and electronic records do not meet employee accountability/responsibility policy and signature manifestation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records;

(12) "[t]he document control procedures do not designate an individual to review documents for adequacy and approve them prior to issuance;"

(13) "[r]ework and reevaluation activities have not been documented in the device history records;"

(14) "[d]ocument control procedures are not complete;" and

(15) the device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Feb. 8 FDA 483 at 1-6.

173. The findings of the FDA inspection of August and September 2005 confirm that Guidant was violating federal and state law in manufacturing the Devices.

174. From December 2005 to February 2006, the FDA again inspected Guidant's manufacturing facilities and found further egregious violations of basic manufacturing standards fundamental to federal and state law. *See* Feb. 8 FDA 483. Specifically, the FDA found that Guidant had failed to disclose the AVT device defects that it had known about since May 2002 and had attempted to correct through revised software implemented by May 2004. *See id.*

175. The FDA's inspections led to recalls of Guidant Devices at issue in this litigation and specifically criticized Guidant's manufacturing and disclosure processes, stating that Guidant had failed to establish adequate procedures in violation of federal regulations.

176. Moreover, with respect to each of the Guidant Devices at issue in this litigation, Defendants failed to comply with FDA regulations and the Conditions of Approval relating to relevant PMA and PMA Supplements.

177. The claims alleged herein set forth sufficient facts to establish manufacturing defects with respect to the Guidant Devices.

178. No claims alleged herein are preempted under any provisions of the Medical Device Act or FDA regulations.

179. Guidant's failure to meet federal regulations applicable to medical devices and Guidant's other acts and omissions as described herein directly and proximately caused the Devices to be in violation of federal and state law, and proximately caused harm and injury to Plaintiffs.

B. Guidant's Concealment of the Device Defects

180. Guidant's failure to disclose accurately and adequately the known defects in the Devices and concealment of known defects from the FDA, the medical community, and from Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

181. No Plaintiff could have discovered the existence of the short-circuit defect in the Ventak Prizm 2DR 1861, until at least May 2005, when the first press reports regarding the defects were published. It was not until June 17, 2005, that the public was officially notified by the FDA that Guidant was voluntarily withdrawing the Ventak Prizm 2 DR 1861 from the market.

182. It was not until June 17, 2005, that the public was officially notified by the FDA that the agency was recalling Contak Renewal 1 & 2 devices. At no point prior to June 17, 2005, did Guidant notify any Plaintiff, the medical community, or the public that the Contak Renewal 1 & 2 were defective.

183. It was not until June 17, 2005, that the public was notified by the FDA that AVTs were defective and were resulting in memory failures. At no point prior to June 17, 2005, did Guidant notify any Plaintiff, the medical community, or the public that the AVTs were defective.

184. It was not until July 2005 that the public was officially notified that the Guidant Pacemakers were defective. At no point prior to July 22, 2005 did Guidant notify any Plaintiff, the medical community, the FDA, or the public that the Guidant Pacemakers were defective.

185. Meanwhile, although Guidant regularly issued Product Performance Reports purporting to disclose information regarding the Devices, it was not until late 2005 that such Product Performance Reports included any information from which a reader could discern that Guidant was aware of potentially life-threatening malfunctions that could occur in the Devices.

186. Guidant's failure to properly disclose the known defects in the Devices and their active concealment of the known defects from the FDA, the medical community, and Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

187. Guidant is estopped from relying on the statute of limitations defense because it actively concealed the ICD defects by suppressing reports, failing to follow through on FDA

notification regulations, and failing to disclose known defects to the medical community, the public, or the Plaintiffs. Instead of revealing the defects, Guidant continued to represent the Devices as safe for their intended use.

188. Guidant's conduct, as described in the preceding paragraphs, amounts to conduct that Guidant must have realized was dangerous, heedless and reckless, without regard to the consequences or to the rights and safety of Plaintiffs.

189. At all times relevant to this action, Guidant knew, and had reason to know, that the Devices were not safe for the individuals for whom they were prescribed and implanted, because the Devices short circuited and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some individuals, catastrophic injuries and deaths.

190. As a result of defects in both the design and the manufacture of the Devices, Guidant knew and had reason to know that the Devices would fail to function properly, and have a significantly decreased life expectancy – which was concealed from the FDA, the medical community, and the individuals in whom the Devices were implanted.

191. Further, Guidant knew and had reason to know that the life expectancy of the Devices was significantly shorter than that which Guidant represented to the FDA, the medical community, and those in whom the Devices were implanted. Guidant affirmatively concealed and suppressed the true information about the life expectancy and reliability of the Devices.

192. At all times relevant to this action, Guidant knew, and had reason to know, that the Ventak Prizm 2 DR 1861 and Contak Renewal 1 & 2 were not safe and effective for the individuals for whom they were prescribed and implanted, because after short circuiting the Devices could fail to function and the internal memory within the Devices would be erased, thereby concealing both

evidence of the short circuit and any medical memory of the patient's arrhythmias in the period preceding the short-circuiting episode. This malfunction prevents the doctor from properly reviewing the patient's heart rhythm history, and from providing related medical services, such as possibly adjusting necessary medication. Further, while Guidant has recommended that doctors consider inducing shocks to their patients to determine if the devices are already malfunctioning, it is otherwise impossible for doctors to test these devices to determine whether they will short circuit and fail to perform as intended.

193. Nonetheless, in its June 24, 2005 letter to patients, Guidant continued to falsely reassure the public that "[t]he safety and well being of patients is foremost in our minds" and that Guidant maintains a "steadfast dedication to patients." Letter from Allan Gorsett, Vice President, Reliability and Quality Assurance, Guidant Corp., to Patients with Contak Renewal 1 & 2 Devices at 1 (June 24, 2005).

194. The Independent Panel, however, found that Guidant's quality control processes – particularly with respect to post-market evaluation of the Devices – are not consistent with appropriate concern for patients and quality. For example, the Independent Panel concluded that no medical professionals are involved in Guidant's post-market surveillance, that positions critical to the assessment of Device defects were consistently understaffed by Guidant, and that the few individuals who were assigned to the important task of assessing Device defects generally lacked sufficient appropriate training and expertise.

C. Guidant's Deceptive Promotional and Marketing Activities

195. Consistent with their failure to disclose defects and its other concealments of the defects in the Devices, throughout the years that it was manufacturing and selling the Devices, Defendants' promotional, marketing, and advertising materials consistently concealed the defects

about which it knew or should have known, as set forth at length above. Routinely, the information provided in those materials was materially misleading and incomplete. While otherwise affirming aspects of the Devices, the defects were consistently never disclosed. Illustrative is the following:

VENTAK PRIZM 2 DR
Dual-Chamber, Adaptive-Rate
Model 1861

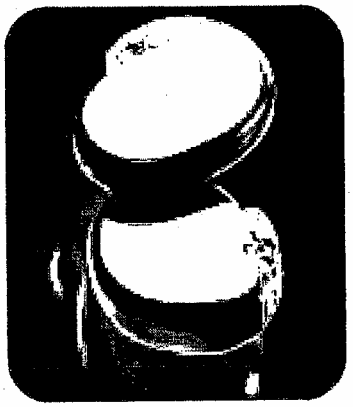
VENTAK PRIZM 2 VR
Single-Chamber, Adaptive-Rate
Model 1860

The Guidant VENTAK® PRIZM 2® AICD automatic implantable cardioverter defibrillators are designed to detect and terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) and provide bradycardia therapy (atrial and/or ventricular pacing). Therapies include both low- and high-energy shocks using either a biphasic or monophasic waveform. The VENTAK PRIZM 2 models use the Guidant TRIAD® electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the Guidant ENDOTAK® two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. VENTAK PRIZM 2 devices also offer a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias.

196. By way of another example, in one marketing brochure, Guidant affirmatively and specifically touted the longevity of its ICDs:

World's smallest, thinnest dual-chamber ICD

World's highest-output sub-40 cc ICD



World's longest-lasting sub-40 cc ICD

197. Another marketing brochure thus advertised the Ventak Prizm's long life:

Long-Lasting Wonders

GUIDANT ICD SYSTEMS

Patients often ask how long their devices will last. It's hardly surprising—they know their lives depend on them. In a recent survey of 137 ICD recipients, 90 patients indicated the longevity of their ICD is a primary concern.*

Give your patients the comfort of knowing they have a Guidant ICD system with the stamina to perform over the long haul . . . systems with the best combination of size and longevity, backed by the world's longest warranty package.

In reality, Defendants' devices did not have such longevity and by virtue of the defects inherent in the products, Plaintiffs and many other individuals have had to have their devices prematurely explanted long before the expected life of the products had run.

D. Guidant's Continued Failure To Provide Adequate and Accurate Information

198. Tens of thousands of individuals' lives rely upon the proper functioning of the Devices, and they – along with their physicians – have been vigorously attempting to assess the risks that they now face.

199. Yet, due to Guidant's delayed disclosure and shifting positions, individuals and physicians remain uninformed and confused about whether the Devices should be explanted, or whether all of the defects have been disclosed.

200. Guidant sales representatives consistently visit with individuals and physicians, attempting to persuade them that, notwithstanding the various FDA Class I recalls, explantation of the Devices is unnecessary.

201. It remains unclear how many individuals are affected by the defective Devices, although based on the population of Guidant individuals whose claims are asserted in this and other federal complaints, it is likely to be at least 80,000 individuals in the United States. Although Guidant should have records regarding the Devicies, information on the number of affected individuals from Guidant is variable and confusing:

- Guidant originally reported that some 24,000 currently-implanted Ventak Prizm 2 DR 1861 devices worldwide were at risk of failure. *See* May 25 Guidant Press Release.
- Guidant later informed the New York Times that the total number of Ventak Prizm 2 DR 1861 devices implanted with the defective design was 37,000. *See Flawed Implants: Disclosure and Delay*.
- According to the June 17, 2005 Dear Doctor Letter, an additional 20,950 devices were subject to failure. *See* June 17 Dear Doctor Letter at 1.

- In a June 23, 2005 letter to physicians, Guidant reported that a further additional 46,000 devices were subject to failure. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Contak Renewal 3 and 4, Renewal 3 and 4 AVT, Renewal RF at 1 (June 23, 2005).

202. FDA estimates have put the total number of potentially affected Devices at 87,600, including 20,600 Devices with deteriorated electrical insulation (such as the Ventak Prizm 2 DR 1861); 21,000 Devices with the "latching" error (such as the AVTs); and 46,000 Devices with the malfunctioning magnetic switch (such as the Contak Renewal 3 & 4).

203. Information on what individuals implanted with one of the Devices should do is similarly confusing. For example, in June 2005, Guidant stated that it "does not recommend routinely using a commanded shock to detect the shorting problem" in the Ventak Prizm 2 DR 1861. June 17 Dear Doctor Letter at 2. In December 2005, Guidant notified physicians that they "may choose to perform a commanded shock to confirm integrity of the high voltage delivery circuit." Advisory Update: Ventak Prizm 2 DR Model 1861 (Dec. 20, 2005).

E. Guidant's History of Criminal Misconduct

204. In June 2003, Guidant's then wholly-owned subsidiary, Endovascular Technologies, Inc. ("EVT"), agreed to plead guilty to nine felony counts of introducing misbranded medical devices into interstate commerce, in violation of 21 U.S.C. § 331(a), and one felony count of making false statements to the FDA, as well as the payment of $92.4 million to settle the charges. The plea agreement related to a medical device known as the Ancure Endograft System, which was released in September 1999, withdrawn in March 2001, released again in August 2001, and finally withdrawn in March 2003. The device was used to treat abdominal aortic aneurysms, a potentially life-threatening condition. Guidant's EVT subsidiary became aware of serious and sometimes fatal malfunctions in the device's delivery system, yet concealed information about the malfunctions

from the FDA, physicians, and the public. At least seventy-six deaths and dozens of invasive surgeries resulted from the malfunctions.

205. The FDA sought criminal punishment and civil fines for Guidant's failure to uphold its "serious responsibility to report deaths and injuries associated with [its] products to the FDA." *See* http://www.fda.gov/fdac/departs/2003/603_irs.html (reflecting information originally published in FDA Consumer Magazine Volume 37, Number 6 | November-December 2003). The settlement required Guidant to enter into a Corporate Integrity Agreement with the Office of the Inspector General of the Department of Health and Human Services, Guidant's violation of which is the subject of the current FDA inquiry.

206. The Corporate Integrity Agreement required Guidant to develop and maintain practices and procedures to assure its compliance with federal law, including compliance with the MDR procedures set forth in 21 C.F.R. § 803, the failure analysis and quality assurance procedures set forth in 21 C.F.R. § 820, and the recall and notification procedures set forth in 21 C.F.R. § 806. The Corporate Integrity Agreement also required Guidant to develop and maintain practices and procedures to comply with 21 C.F.R. § 814 concerning device modifications, instructions for use, pre-market approval conditions and to comply with 21 C.F.R. §§ 803, 806 and 820, concerning maintaining MDRs, implementing device Removals and Corrections, and establishing Quality Systems. The Corporate Integrity Agreement also specified that Guidant must comply with the federal regulations for reporting adverse events, or MDRs, in accordance with 21 U.S.C. § 360i.

207. Despite the obligations described above in the Corporate Integrity Agreement executed by Guidant on June 30, 2003, Guidant failed to satisfy those obligations in its manufacture and sale of the Devices.

208. For example, as to the Devices, Guidant failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

209. Moreover, as the Independent Panel concluded, Guidant's policies and practices with respect to internal communications and review of device defects were seriously lacking in several regards, in a manner wholly inconsistent with Guidant's duties under the Corporate Integrity Agreement to maintain policies and procedures that ensure compliance with federal device safety regulations. As one example, the Independent Panel concluded that Guidant did not have uniform corporate wide practices for quality control, corrective action, risk assessment, risk management, and public communications.

210. According to a June 16, 2005, Minneapolis newspaper article, federal regulators have begun an inquiry into whether Guidant has violated the Corporate Integrity Agreement, signed by its wholly-owned subsidiary in 2003, in the wake of civil and criminal charges related to a different malfunctioning medical device and Guidant's attendant attempt to cover up the incidents of malfunction. *See* Janet Moore, *Federal Inquiry Looks at Guidant Case*, Star-Tribune, June 16, 2005.

211. Guidant clearly has a history of withholding information from the FDA, the medical community and its customers, and has previously pleaded guilty to criminal and civil charges for failing to provide accurate data about other defective products. Guidant's conduct shows a reckless disregard for public health and the safety of its customers. In the context of its past criminal history

and its recent violation of the Corporate Integrity Agreement, Guidant's conduct in this situation has been particularly egregious. For this and other reasons, Plaintiffs submit that punitive damages claims, raised when and as appropriate under governing law, will prove to be warranted in this case.

F. The Guidant Co-Defendants Are Agents and Alter Egos of One Another

212. At all times herein mentioned, each of the Guidant Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Guidant Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Guidant Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiffs.

213. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Guidant Defendants such that any individuality and separateness between them has ceased and all the Guidant Defendants are the alter ego of the other Guidant Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of the Guidant Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

214. At all times herein mentioned, the Guidant Defendants together, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiffs. As such, each Defendant is individually, and jointly and/or severally, liable to Plaintiffs for Plaintiffs' damages.

215. The Guidant Defendants acted jointly in the concerted tortuous conduct alleged herein.

216. At all times herein mentioned, the officers and/or directors of the Guidant Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned Devices when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said Devices, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiffs.

217. Boston Scientific, by acquiring the Guidant Defendants, apparently with full knowledge of their actions, has assumed the liabilities of the Guidant Defendants.

VI. THE MEDICARE AS SECONDARY PAYER STATUTE

218. Medicare is a health insurance program for the elderly and disabled, and is funded by the workers of America via contributions through payroll deductions. Under the Medicare program, the federal government pays for certain health care expenses of the aged (persons who are sixty-five years of age and older), the disabled, and persons suffering from end stage renal disease. The Medicare program is the second largest social insurance program in the United States, with 41 million beneficiaries and total expenditures of $280.8 billion in 2003. The Trustees of Medicare have reported "the projected financial status of Medicare has taken a major turn for the worse." It is estimated that by year 2019, the Medicare Hospital Insurance Trust Fund will likely be bankrupt.

219. According to governmental studies, the majority of ICD recipients are sixty-five years of age or older and are thus eligible for coverage under the Medicare program. As an example, in the State of Connecticut for fiscal year 2004, Medicare paid for nearly 65% of all ICD therapy. In 2002 total Medicare reimbursements for ICD procedures were approximately $1.2

billion. In 2003, the Center for Medicare and Medicaid Services paid for 52,500 ICD implantations; in 2004, it paid for 65,000.

220. Medicare originated as a series of amendments to the Social Security Act. The Medicare as Secondary Payer ("MSP") statute is codified as 42 U.S.C. § 1395y(b). The MSP, in its present form, originated with the enactment of the Omnibus Budget Reconciliation Act ("OBRA") of 1980, Pub. L. No. 96-499, § 953, 94 Stat. 2647 (1980). The MSP was enacted in 1980 to reduce the Medicare program's rising costs. *See* H.R. Rep. No. 1167 (1980). The MSP statute functioned to reduce Medicare spending, as well as to insure the financial integrity of the Medicare program.

221. The MSP provides that liability insurance is included as a source of payment from a primary payer. The regulations adopted pursuant to MSP declare: "Liability insurance means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to . . . product liability insurance . . . ." 42 C.F.R. 411.50.

222. The MSP contemplates a right to recovery based on ongoing litigation against primary plans and settled claims paid by primary plans. 42 U.S.C. § 1395y(b)(2)(B)(ii). The MSP also contemplates a right to recovery from both first party insurance coverage and/or third party (tortfeasor) insurance coverage (first party insurance coverages described in the statute include group health plans, large group health plans, workmen's compensation plans and no-fault insurance; third party insurance coverages described in the statute include automobile insurance and liability insurance). *See id.* § 1395y(b)(2)(A).

223. Since enacting the MSP statute, Congress has repeatedly clarified and augmented the Government's powers to recoup conditional Medicare payments from primary sources.

224. The Deficit Reduction Act ("DERFA") of 1984 conferred on the Government a direct right of action to recover its payments from any entity "which would be responsible for payment," under a, "law, policy, plan or insurance." *See* Pub. L. No. 98-369, 98 Stat. 494 (1984).

225. In OBRA 1986, Congress added a private right of action for double damages codified at 42 U.S.C. § 1395y(b)(3)(A). It also cross-referenced to § 1395y(b)(2)(B)(ii), which enables the Government to collect double damages "in accordance with" the new private right of action. H. Res. 5300, 99th Cong. (1986) at § 9319.

226. The MSP was again amended in 2003 under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Modernization Act"), Pub. L. No. 108-173, § 301, 117 Stat. 2221, which clarified that conditional Medicare payments may be made but that the government retains the right to recover such payments from any responsible entity. When Congress passed the Modernization Act, it amended the MSP to expand the scope of actions to include "any or all entities that are or were required or responsible . . . to make payment . . . under a primary plan" (the prior statute referred to "any entity"). *Id.* § 301(b)(3).

227. The Modernization Act provides that "[a]n entity…shall be deemed to have a self-insured plan if it carries its own risk (whether by failure to obtain insurance, or otherwise) in whole or in part," plainly clarifying that the term "self-insured plan" should have always been broadly interpreted. *Id.* § 301(b)(1); *see also* H.R. Rep. No. 108-178, pt. 2, at 189-90 (stating that the reason for adding the definitional sentence was to remedy the effects of "[r]ecent court decisions" that would allow "firms that self-insure for product liability" to be "able to avoid paying Medicare for past medical payments related to the claim").

228. The Modernization Act provides that a primary plan shall reimburse Medicare for any payments Medicare has made if it is demonstrated that such primary plan has or had a responsibility to make such payments.

229. The Modernization Act provides that "[t]he United States may bring an action against *any or all entities that are or were required or responsible* (directly, as an insurer or self-insurer . . . or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan." *Id.* (emphasis added). The Modernization Act deleted the parenthetical phrase "including any physician or provider," thus further clarifying that the category of entities liable to reimburse Medicare was not to be narrowly interpreted.

230. The MSP statute, along with the legislative history of the 2003 amendments, make clear that Medicare payments can be recovered from tortfeasors, both directly from the tortfeasor and as part of the private right of action permitted under the MSP.

231. As currently codified, 42 U.S.C. §1395y(b)(2), the MSP provides, in relevant part, as follows:

> (2) Medicare secondary payer.
>
> > (A) In general.
> >
> > Payment . . . may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that . . . payment has been made or can reasonably be expected to be made under a . . . liability insurance policy or plan (including a self-insured plan) . . . . [T]he term "primary plan" means a . . . liability insurance policy or plan (including a self-insured plan) . . . . An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.
> >
> > (B) Repayment required
> >
> > > (i) Authority to make conditional payment. The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make a payment with respect to such item or service promptly . . . .

> (ii) Repayment plans.
> A primary plan, and an entity that receives payment from a primary plan, shall reimburse . . . with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.
>
> (iii) Action by United States
> In order to recover payment made under this [title] for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer . . .) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.
>
> * * *
>
> (3) Enforcement.
>
> (A) Private cause of action.
> There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

42 U.S.C. § 1395y(b)(2), (b)(3).

232. The MSP provides that liability insurance is included as a source of payment from a primary payer. The regulations adopted pursuant to the MSP state that Medicare payments can be recovered from, e.g., products liability insurance. *See* 42 C.F.R. § 411.50.

233. Under the provisions of the MSP (as amended by the Modernization Act) Guidant: (i) is a primary plan, (ii) that is responsible to pay for an item or service, and (iii) that has failed and/or refused to make appropriate payment to Medicare for the item or device.

234. The MSP, requires a primary plan like Guidant to reimburse Medicare "if it is demonstrated" that the primary plan "has or had a responsibility" to make payment for an item or service. Applying this plain language, it is clear that Guidant has or had such a responsibility but that it is improperly passing on this burden to the Medicare.

235. Guidant is considered a primary plan under the MSP and is responsible to fully reimburse Medicare for the Devices. Guidant is a primary payer under MSP's first party insurer provisions. Guidant has agreed to make payment of out of pocket expenses as part of its extended warranty programs. Guidant has an extensive website which provides detailed instructions on how to make claims to Medicare for reimbursement of medical expenses related to its ICD Devices. Guidant recognizes on its website that medical costs incurred in connection with review, repair and replacement of the recalled devices will be borne by Medicare. Guidant has either knowledge or constructive knowledge that some of the recipients of the funds they are paying out had received ICD-related medical treatment for which Medicare already paid. As a result, Guidant is liable to reimburse the government pursuant to MSP.

236. Guidant is also a primary payer under MSP's third party tortfeasor insurer provisions. Guidant carries liability insurance from which a payment can reasonably be expected to be made.

237. According to Guidant's SEC filings, Guidant conducts its business pursuant to plans under which it acquires product liability insurance and also self-insures for product liability and warranty exposures. On February 15, 2005, Guidant reported that "[p]roduct liability insurance remains available to the Company on terms consistent with those available in prior periods. However, like many of its industry peers, the Company has elected to increase substantially the

degree to which it self-insures for product liability exposures." Guidant Corp., SEC Form 10-K for fiscal year ended December 31, 2004 at 9 (SEC filed Feb. 15, 2005).

238. On February 22, 2006, Guidant's SEC filing reported that, after September 1, 2005, Guidant adopted a plan of self-insurance for product liability exposures. Guidant's insurance coverage plan had previously contained substantial self-insurance retentions which required the recordation of estimated expenses at the time a device is sold based upon historical experience, anticipated changes and failure rates. These retentions were thereafter evaluated quarterly under the plan and "warranty cost accruals" were adjusted.

239. That same 2006 SEC filing indicates that Guidant records charges based on the number of devices which it expects physicians to replace according to a review of factors including device failure rates and FDA recall classifications. The plan recorded charges for anticipated supplemental warranty claims under the plan.

240. Guidant's liability insurance policies or plans, including its self-insured plans, are "primary plans" under the MSP statute making Guidant obligated to provide primary payment for the health care expenditures resulting from the implant of the Devices.

241. Guidant's obligation to pay for the MSP ICDs has already been established. The FDA has recalled the MSP ICDs and classified the recalls as Class I and Class II indicating the seriousness of the matter as affecting the health and safety of device recipients. Guidant has admitted the defects inherent in the MSP ICDs. Guidant has established a program and/or agreement as part of its "supplemental replacement policy" to pay (under limited and specified conditions) for certain costs associated with the replacement of the MSP ICDs. Guidant has expressly agreed to provide a replacement device for certain of the MSP ICDs (from its inventory

of ICDs) and to provide un-reimbursed medical expenses (after Medicare payments) to patients for out-of-pocket expenses up to $2500.

242. Guidant's responsibility to make payment has been further demonstrated by the existing contractual relationship between Guidant (as the primary payer) and the Medicare beneficiaries. In addition to, and without limiting the other express and implied warranties provided by Guidant related to the MSP ICDs, Guidant (i) expressly warranted the MSP ICDs for five to seven years upon sale and (ii) via its extended warranty program following the recall has established a supplemental replacement policy for the MSP ICDs. As evidenced by various news accounts and The New England Journal of Medicine, a large percentage of patients have already determined to have the MSP ICDs surgically replaced following news of the recall.

243. Guidant also directed its tortious conduct with respect to the Devices to Medicare, by actively participating in efforts to obtain Medicare payments for the Devices. The Guidant website states, under the prominent heading "Reimbursement," that Guidant "work[s] directly with the Centers for Medicare and Medicaid Services (CMS), public and private health insurers, and industry stakeholders to ensure appropriate reimbursements for services involving our products." Guidant Corp., *Reimbursement*, http://www.guidant.com/reimbursement/ (last visited April 23, 2006. Further, Guidant provides detailed instructions to medical providers interpreting Medicare reimbursement guidelines and recommending how to bill Medicare for costs resulting from the Devices, which costs are in fact Guidant's primary responsibility under the MSP.

244. Guidant has pursued a means of wrongfully passing on to Medicare costs resulting from the Devices. On July 18, 2005, Guidant posted on its website a notice entitled "Reimbursement Guidelines For Device Replacements Due to a Recall." These guidelines instructed medical providers on how to bill Medicare for device replacements due to a recall (as

well as hospital, physician and other related medical costs). Guidant's reimbursement guidelines advised and recommended as follows: "According to Medicare policy, device replacements may be reimbursed by either the liable party or Medicare. However, note that Medicare specifically states [w]hen defective equipment or a defective medical device is replaced under a warranty, hospital or other provider services rendered by parties other than the warrantor are covered despite the warrantor's liability." Guidant Corp., Reimbursement Guidelines for Device Replacements Due to a Recall at 1 (July 18, 2005) (internal quotation marks omitted).

245. Guidant's website further recommends and instructs providers how to obtain from Medicare the additional medical costs associated with monitoring the Devices. The Guidant website instructs as follows:

> Device Follow-Ups for Recalled Devices. Currently,CMS has no national guidelines regarding the number of times a patient can have an ICD or CRT-D device checked within a calendar year. Guidant recommends device check-ups at least four times per year, but physicians establish device follow-up schedules based on each patient's needs. In our experience, most payers, including CMS, have reimbursed providers for additional follow-ups based on medical necessity if medically necessary and indicated.

Id. at 2.

246. Consistent with and as further evidence of Guidant's wrongful plan to pass on to Medicare the full costs of replacement for its defective devices, Guidant recently published on its website a notice relating to the Class I recall of Guidant Pacemakers and Guidant's so-called "supplemental warranty program" which reads in pertinent part as follows:

> Guidant will provide a replacement device at no charge for pacemaker-dependent patients and other patients deemed by their physicians to be best served by replacement . . . . Additionally, Guidant will reimburse patients up to $2,500 for medical expenses remaining after Medicare and/or health insurance coverage, including device replacement or additional follow-up procedures. Guidant's policies and practices are similar for all the Devices.

Guidant Corp. News Release, Guidant Initiates Worldwide Physician Communications Regarding Important Safety Information and Corrective Action about Pacemakers (July 18, 2005).

247. Guidant's offer to replace certain of the Devices from its inventory of other products is unsatisfactory to most affected individuals, given the loss of confidence in Guidant in light of the many recalls and advisories relating to the Devices and the revelation of Guidant's concealment of information relating to defects in the Devices. As reported in the June 8, 2005 article entitled "Guidant Recalls Heart Aids" published in the Twin Cities Pioneer Press, Dr. Robert Hauser, a cardiologist at Minneapolis Heart Foundation, was quoted as saying for his patients, "Most choose to go with a [non-Guidant] device."

248. Further, Guidant's offer to reimburse some recalled Guidant ICD patients up to $2500, for a limited period of time, for medical expenses remaining after Medicare, health insurance coverage, or both, constitutes an implicit admission that there are substantial other costs to be borne by Medicare, e.g., surgery and other medical service fees and costs resulting from replacement of the Devices, including expenses relating to subsequent monitoring and possible complications from surgery.

249. Guidant is liable for such costs. Under the MSP (as amended by the Modernization Act) Guidant: (i) is a primary plan, (ii) that is responsible to pay for an item or service, and (iii) that has failed and/or refused to make appropriate payment to Medicare for the item or device.

250. The damages to Medicare hereunder are ascertainable. Such damages are twice the amount of Medicare's actual health care expenditures resulting from the Devices implanted in Medicare beneficiaries. The amount of damages is ascertainable from various sources including information set forth in the computerized public use data files maintained by the Center for

Medicare and Medicaid Services ("CMS"). These data files contain Medicare reimbursement amounts that are matched with the universally recognized system of procedure codes.

251. The MSP statute provides that a private cause of action may be brought against any entity, such as Guidant, that wrongfully shifts the burden of medical costs to Medicare. Guidant cannot be permitted to "pass the buck" to Medicare in its responsibility for the full payment of the health care expenditures related to the Devices.

252. Guidant has a history of defrauding Medicare. As a result of the plea agreement that led to the Corporate Integrity Agreement, Guidant's EVT Division agreed to pay the federal government $92.4 million, which included a forfeiture of $10.9 million, a criminal fine of $32.5 million, and a civil settlement of $49 million to settle claims that the company's actions caused Medicare, Medicaid and the Veterans Affairs Program to pay millions of dollars for the adulterated and misbranded devices.

253. Moreover, in January 2005, while simultaneously concealing information regarding device malfunctions and mechanical defects from physicians, patients, Medicare, and the public regarding the Devices as alleged herein, Guidant aggressively lobbied for increased Medicare coverage for ICDs, which was granted by the CMS.

CLASS ACTION ALLEGATIONS

254. Pursuant to Rule 23 of the Federal Rules of Civil Procedure and subject to the reservations set forth in paragraph 31, above, Plaintiffs bring this action on behalf of themselves and all others similarly situated, as members of at least the two proposed Plaintiff classes. The first consists of all individuals, the Device Recipient Patients, who have been implanted with an Implantable Device, with several subclasses (set out below). The second class is comprised of all third party payors – the "TPPs" – in the United States (or its Territories) who (i) have been issuers or sponsors of a contract, policy or plan that provides medical coverage to natural persons, and (ii) have incurred, pursuant to such contract, policy or plan, full or partial costs for any of the Devices and related medical costs including implantation surgery, replacement surgery, medical monitoring and/or other hospital costs. For purposes of the latter Class definition, third party entities "purchased" the Guidant Devices if they paid some or the entire purchase price. Excluded from Class membership in both Classes are (a) Defendants, including its officers, directors, subsidiaries and affiliates, any entity in which Defendants have a controlling interest or which have a controlling interest in Defendants, and Defendants' legal representatives, predecessors, successors and assigns; (b) governmental entities (including Medicare)[1]; (c) Plaintiffs' counsel; (d) the Judges of the Court to which this case is assigned; and (e) any member of the immediate families of any excluded persons.

255. By subsequent motion the respective Device Recipient and TPP Plaintiffs will seek class treatment of common claims and issues, as appropriate, under Federal Rule of Civil Procedure 23. In addition, while additional discovery is necessary to determine the extent to which specific classes or subclasses are required, at this time, Plaintiffs preliminarily allege that the following

[1] Medicare's claims are specifically brought under this Complaint under the Medicare Secondary Payer Act and therefore are not part of the TPP subclass.

subclasses for the Device Recipient Patients may be appropriate. The fact the some of the devices fall into two subclasses does not compromise the efficacy of certifying the indicated subclasses.

a. The Short-Circuit Defect Subclass

256. All residents and domiciliaries of the United States (or its Territories) or outside the United States (or its Territories) other than TPPs who have paid in whole or in part for, or have been implanted with the following Devices, all of which are subject to a Class I recall by the FDA because they may short circuit due to deterioration in a wire insulator within the lead connector block include:

Device Family	Models
Contak Renewal	H135
Contak Renewal 2	H155
Ventak Prizm 2 DR	1861

b. The Loss of Hermetic Seal Defect Subclass

257. All residents and domiciliaries of the United States (or its Territories) or outside the United States (or its Territories) other than TPPs who have paid in whole or in part for, or have been implanted with the following Devices manufactured between November 25, 1997 and October 26, 2000, all of which are subject to a Class I recall by the FDA because a hermetic seal with the devices can leak, allowing moisture to affect the electric circuits and cause heart failure or death include:

Device Family	Models
Contak TR	1241
Discovery	1174, 1175, 1273, 1274 or 1275
Discovery II	0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285 or 1286
Intelis II	1349, 1384, 1385, 1483, 1484, 1485 or 1499
Meridian	0476, 0976, 1176 or 1276
Pulsar	0470, 0870, 0970, 0972, 1172 or 1272
Pulsar Max	1170, 1171 or 1270
Pulsar Max II	1180, 1181 or 1280
Virtus Plus II	1380 or 1480

c. The Latching Defect Subclass

258. All residents and domiciliaries of the United States (or its Territories) or outside the United States (or its Territories) other than TPPs who have paid in whole or in part for, or have been implanted with the following Devices, all of which are subject to a Class II recall by the FDA because latching of the devices will suspend detection and treatment of atrial and ventricular arrhythmias include:

Device Family	Models
Contak Renewal 3 AVT	M150 or M155
Contak Renewal 3 AVT HE	M157 or M159
Contak Renewal 4 AVT	M170 or M175
Contak Renewal 4 AVT HE	M177 or M179
Ventak Prizm AVT	1900
Vitality AVT	A135, A155

d. The Magnetic Switch Defect Subclass

259. All residents and domiciliaries of the United States (or its Territories) or outside the United States (or its Territories) other than TPPs who have paid in whole or in part for, or have been implanted with the following Devices, all of which are subject to a Class II recall by the FDA because a magnetic switch in these devices may become stuck in the closed position, which may inhibit the device's ability to treat ventricular or atrial tachyarrhythmia and can accelerate battery depletion include:

Device Family	Models
Contak Renewal 3	H170, H173 or H175
Contak Renewal 3 AVT	M150 or M155
Contak Renewal 3 AVT HE	M157 or M159
Contak Renewal 3 HE	H177 or H179
Contak Renewal 4	H190 or H195
Contak Renewal 4 AVT	M170 or M175
Contak Renewal 4 AVT HE	M177 or M179
Contak Renewal 4 HE	H197 or H199
Renewal RF	H230 or H235
Renewal RF HE	H239

260. An additional subclass or subclasses may be necessary for certain failure modes identified by Guidant with respect to its Insignia and Nexus implantable heart pacemakers. Guidant has identified that the Devices may experience intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, or reversion to VVI mode or appearance of a reset warning message upon interrogation. Guidant has identified the root cause of one failure mode as foreign material within a crystal timing component. Guidant has not indicated that it has determined the root cause of other failure modes. Accordingly, it is premature to even make a preliminary determination at this time as to the proper class treatment of these devices. The affected devices are:

Device Family	Models
Insignia AVT DDD	0982
Insignia AVT DR	1292
Insignia AVT SR	1192
Insignia AVT SSI	0482
Insignia AVT VDD	0882
Insignia Entra DR	1294, 1295 or 1296
Insignia Entra SR	1195 or 1198
Insignia Entra SR DDD	0985 or 0986
Insignia Entra SSI	0484 or 0485
Insignia Plus DR	1297 or 1298
Insignia Plus SR	1194
Insignia Ultra DR	1290 or 1291
Insignia Ultra SR	1190
Nexus AVT DDD	1432
Nexus AVT DR	1492
Nexus AVT SR	1392
Nexus AVT SSI	1328
Nexus AVT VDD	1428
Nexus Entra DDD	1425 or 1426
Nexus Entra DR	1466, 1494 or 1495
Nexus Entra SR	1395 or 1398
Nexus Entra SSI	1325 or 1326
Nexus Plus DR	1467 or 1468
Nexus Plus SR	1394
Nexus Ultra DR	1490 or 1491
Nexus Ultra SR	1390

e. Medical Monitoring Subclass

261. All members of the Device Recipient Class and/or the preceding Device Recipient Subclasses that currently have Implantable Devices implanted within them.

f. General Class Allegations

262. This action is brought and may properly be maintained as a class action pursuant to the provisions of Federal Rules of Civil Procedure 23(a)(1)-(4), (b)(2) and (3), and/or 23(c)(4)(A). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

263. One or more of the Plaintiffs is a member of and has standing to represent at least one of the Classes and/or Subclasses described above.

264. The Device Recipient Class and each of its Subclasses are so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery of Defendants, Plaintiffs are informed and believe that the Device Recipient Class includes more than 87,000 patient recipients worldwide and the TPP Class includes seven thousand TPPs. Over 33,000 of the devices included in the Short Circuit Defect Subclass were implanted in members of the Class at or about the time this action was commenced; approximately 18,000 of the devices included in the Hermetic Seal Defect Subclass were implanted in members of the Class at or about the time this action was commenced; approximately 21,000 of the devices included in the Latching Defect Subclass were implanted in members of the Class at or about the time this action was commenced; approximately 46,000 of the devices included in the Magnetic Switch Defect Subclass were implanted in members of the Class at or about the time this action was commenced;

and approximately 41,000 of the Insignia and Nexus devices at issue were implanted in Class members at or about the time this action was commenced.

265. Common questions of fact and law exist as to all members of the Classes that predominate over any questions affecting only individual members of the Classes. These common legal and factual questions, which do not vary from class member to class member, and which may be determined without reference to the individual circumstances of any class member, include, but are not limited to, the following:

a. Whether there are design and/or manufacturing defects in the Devices;

b. Whether Defendants negligently and/or fraudulently distributed, promoted, tested, sold, and/or marketed the Devices;

c. Whether Defendants failed to follow appropriate manufacturing practices as required by FDA regulations in manufacturing the Devices;

d. Whether Defendants' conduct in designing, manufacturing, and marketing the Devices fell below the applicable duties of care owed by Defendants to the Plaintiffs and class members;

e. Whether Defendants' have violated and failed to comply with their obligations under the Corporate Integrity Agreement;

f. Whether Defendants intentionally, deliberately, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed or suppressed material and important information regarding the existence of defects in the Devices from Plaintiffs, class members, and physicians;

g. Whether any claims asserted herein are preempted under federal law;

h. Whether Defendants are liable for selling dangerous Devices;

i. Whether Defendants failed to adequately warn or notify patient recipients, the medical community, and the regulators of the defect, dangers, disadvantages and hazards of the Devices, both before implant and after;

j. Whether Defendants failed to adequately warn or notify hospitals and physicians regarding the defect, malfunction and/or hazards of the Devices, both before implant and after;

k. Whether Defendants' conduct constitutes negligence;

l. Whether Defendants' misconduct violated applicable uniform deceptive acts and trade practices and/or consumer fraud and consumer protection statutes;

m. Whether Defendants' misconduct constitutes breaches of any warranties recognized by law;

n. Whether Plaintiffs and members of the Classes are entitled to injunctive and other equitable relief, including restitution and disgorgement, and if so, the nature of such relief;

o. Whether Plaintiffs and class members are entitled to the benefit of a Court-supervised program of medical monitoring and surveillance, and medical treatment at Defendants' expense;

p. Whether Plaintiffs and class members are entitled to compensatory damages and/or restitution, and if so, the method by which such relief should be determined;

q. Whether Defendants are liable for punitive or exemplary damages, a matter to be determined when appropriate, and if so, the amount necessary and appropriate to punish them for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages, if such claims are permitted by the Court as appropriate, as set forth in controlling Supreme Court authority; and

r. Whether Defendants unjustly enriched themselves at the expense of Plaintiffs and class members, and, if so, the method by which relief should be provided to Plaintiffs and the class members.

266. The respective Plaintiffs' claims are typical of the claims of the members of the respective Classes and applicable Subclasses. Plaintiffs and all members of the Classes, and/or Subclasses, have the same types of damages and are facing irreparable harm and further damages arising out of Defendants' common course of conduct as alleged herein.

267. Plaintiffs are adequate representatives of the Classes and applicable Subclasses because their interests do not conflict with the interests of the members of the Classes and Subclasses they seek to represent. Plaintiffs have retained counsel competent and experienced in the prosecution of products liability, mass torts, deceptive or unfair trade practices and consumer fraud class actions, and together Plaintiffs and their counsel intend to prosecute this action vigorously for the benefit of the Classes and Subclasses. The interests of Class and Subclass members will fairly and adequately be protected by Plaintiffs and their respective counsel.

268. A class action is superior within the meaning of Federal Rule of Civil Procedure 23(b)(3) to other available methods for the fair and efficient adjudication of this litigation since individual litigation of the claims of all class members is impracticable. Even if every class

member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts, in which individual litigation of hundreds, if not thousands, of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race for the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Device Recipient claimants and all TPP class members. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

269. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Federal Rule of Civil Procedure 23(b)(2) because Defendants have acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

CLAIMS FOR RELIEF
DEVICE RECIPIENT PLAINTIFFS

270. Counts I through XVII and XXXI and XXI, below, are asserted on behalf of the Device Recipient Plaintiffs and are subject to the reservations set forth in paragraph 31, above. As used in these Counts the term "Plaintiffs" refers to Device Recipient Plaintiffs.

COUNT I
STRICT LIABILITY – FAILURE–TO–WARN

271. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

272. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Devices. Defendants designed, manufactured, assembled

and sold these Devices to medical professionals and their patients, knowing that they would then be implanted in patients with heart disease and disorders.

273. Defendants distributed and sold the Devices in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Devices were expected to and did reach Plaintiffs without substantial change in their condition as manufactured and sold by Defendants. At no time did Plaintiffs have reason to believe that the devices were in a condition not suitable for their proper and intended use among the patients in whom they were to be implanted.

274. The Devices designed, developed, tested, manufactured, marketed, and sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Devices. Plaintiffs were and are in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Devices.

275. The Devices were implanted and used in the manner for which they were intended, that is, for the detection, correction, and prevention of serious and/or life-threatening harm through surgical implantation. This use has resulted in injury to Plaintiffs.

276. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Devices. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Devices in such a way as to increase the risk of harm, injury or death to the recipients of the Devices.

277. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and

equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT II
STRICT LIABILITY – DESIGN AND/OR MANUFACTURING DEFECT

278. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

279. The Devices are defectively designed and/or manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the Devices.

280. The Devices were designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.* (hereinafter "FDCA"). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Devices were not in conformity with applicable FDCA regulations. The FDA has also concluded that the facilities or controls used by Defendants did not meet the FDCA regulations.

281. The Devices were expected to and did reach the Plaintiffs without substantial change or adjustment to their mechanical function before implantation.

282. Defendants knew or should have known of the design and/or manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Devices.

283. Furthermore, the Devices and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

284. The Devices were defective due to inadequate warnings or instruction because Defendants knew or should have known that the Devices created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers of this risk.

285. The Devices are inherently dangerous for their intended use due to design and/or manufacturing defect and improper functioning. Defendants are therefore strictly liable.

286. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT III
NEGLIGENCE

287. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

288. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiffs to provide a safe product in design and/or manufacture, to notify the FDA of design flaws, to manufacture the Devices properly, and to warn the FDA and Plaintiffs of the defective nature of Defendants' Devices. Defendants breached their duty of reasonable care to Plaintiffs by incorporating a defect into the design of the Devices, thereby causing Plaintiffs' injuries.

289. Defendants breached their duty of reasonable care to Plaintiffs by manufacturing and assembling the Devices in such a manner that they could short circuit and/or otherwise fail to operate and malfunction and expose Plaintiffs to life-threatening physical trauma.

290. Defendants breached their duty of reasonable care to Plaintiffs by failing to notify and warn the FDA, Plaintiffs' treating physicians, Plaintiffs and the public at the earliest possible date of known design or manufacturing defects in the Devices.

291. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

292. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT IV
NEGLIGENCE PER SE

293. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

294. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Devices, and otherwise distributing the Devices.

295. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under theories of negligence per se.

296. Plaintiffs, as purchasers of the Defendants' Devices, are within the class of persons the statutes and regulations described above are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

297. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT V
BREACH OF IMPLIED WARRANTY

298. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

299. Defendants impliedly warranted that their Devices, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were merchantable and fit and safe for ordinary use. Defendants further impliedly warranted that their Devices, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were fit for their particular purposes.

300. Defendants' Devices were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiffs to severe and permanent injuries and death. Therefore, Defendants breached the implied warranties of merchantability and fitness for a particular purpose when their Devices were sold to Plaintiffs, in that the Devices are defective and have short circuited or otherwise failed to function, or are subject to an enhanced risk that they will not function, as represented and intended.

301. Any disclaimers of implied warranties are ineffectual as they were not provided to Plaintiffs or otherwise made known to Plaintiffs. In addition, any such disclaimers are unconscionable.

302. Any purported written warranty fails of its essential purpose.

303. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs have sustained economic losses and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiffs in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages is unconscionable. Defendants are liable to Plaintiffs jointly and/or severally for all damages to which Plaintiffs are entitled by law.

COUNT VI
FRAUD

304. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

305. Contrary to Defendants' representations to Plaintiffs, Defendants' Devices could cause severe injury or death. In fact, short circuits in certain of the Devices were known to Defendants to have occurred for years. At all times during the course of dealing between Defendants and Plaintiffs, directly or through their physicians or other agents, Defendants misrepresented that the Devices were safe and effective for their intended use by affirmative misrepresentation; actively concealed and knowingly or recklessly omitted material facts regarding the safety and effectiveness of the Devices; and/or by their course of conscious or intentional conduct succeeded in selling and marketing dangerous, defective and ineffective medical devices to be implanted in the human body.

306. Defendants, by concealment or other action, intentionally prevented Plaintiffs, Plaintiffs' physicians, and Plaintiffs' other agents from acquiring material information regarding

the lack of safety and effectiveness of the Devices, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Devices' lack of safety and effectiveness, and dangers and defects, as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering, and therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

307. Defendants were under a duty and failed to discharge their duty to exercise reasonable care to disclose to all Plaintiffs the defective nature of the Devices, of which they had special knowledge not available to Plaintiffs, and as to which they made affirmative representations in violation of all applicable laws, including, *inter alia*, *Restatement (Second) of Torts* § 551 (1977).

308. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately or recklessly, in order to induce Plaintiffs to purchase Defendants' Devices and/or agree to have the Devices implanted into their bodies, and Plaintiffs did reasonably and justifiably rely upon the material misrepresentations and omissions made by the Defendants about the Devices when agreeing to purchase and/or have the Devices implanted into their bodies.

309. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiffs have suffered personal injuries and/or pecuniary losses and economic damages, including health care costs that have been paid by them, or on their behalf, in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT VII
CONSTRUCTIVE FRAUD

310. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

311. At the time of selling the Devices to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the devices, which knowledge was not possessed by Plaintiffs, and Defendants thereby held a position of superiority over Plaintiffs.

312. Through their unique knowledge and expertise regarding the defective nature of the Devices, and through their marketing of these devices to be implanted in the human body and statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiffs that they were in possession of facts demonstrating that the Devices were safe and effective for their intended use and were not defective.

313. Defendants' representations to Plaintiffs were unqualified statements made to induce Plaintiffs to purchase the Devices, and Plaintiffs relied upon the statements when purchasing the devices and having them implanted in their bodies.

314. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

315. As a direct and proximate result of Defendants' constructive fraud, Plaintiffs have suffered personal injuries, pecuniary losses, and/or economic damages, including health care costs that have been paid by them, and on their behalf, in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law.

COUNT VIII
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

316. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

317. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Devices.

318. Had the Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Devices, and would not have incurred related medical costs.

319. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

320. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiffs for the Devices that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ala. Code §§ 8-19-1 *et seq*.;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Alaska Stat. §§ 45.50.471 *et seq*.;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ariz. Rev. Stat. Ann. §§ 44-1522 *et seq*.;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ark. Code Ann. §§ 4-88-101 *et seq*.;

e. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Cal. Civ. Code §§ 1770 *et seq*. and Cal. Bus. & Prof. Code §§ 17200 *et seq*.;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or has made false representations in violation of Colo. Rev. Stat. §§ 6-1-105 *et seq*.;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Conn. Gen. Stat. §§ 42-110a *et seq*.;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Del. Code Ann. tit. 6, §§ 2511 *et seq*. and §§ 2531 *et seq*.;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or made false representations in violation of D.C. Code §§ 28-3901 *et seq*.;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Fla. Stat. §§ 501.201 *et seq*.;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ga. Code Ann. §§ 10-1-372 *et seq*.;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Haw. Rev. Stat. §§ 480-1 *et seq*.;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Idaho Code Ann. §§ 48-601 *et seq*.;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of 815 Ill. Comp. Stat. 505/1 *et seq*.;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ind. Code Ann. §§ 24-5-0.5-1 *et seq*.;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Iowa Code §§ 714.16 *et seq*.;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Kan. Stat. Ann. §§ 50-623 *et seq*.;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ky. Rev. Stat. Ann. §§ 367.170 *et seq*.;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of La. Rev. Stat. Ann. §§ 51:1401 *et seq*.;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Me. Rev. Stat. Ann. tit. 5, §§ 205A *et seq*.;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Md. Code Ann., Com. Law §§ 13-101 *et seq*.;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Mass. Gen. L. Ch. 93A *et seq*.;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Mich. Comp. Laws §§ 445.901 *et seq*.;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or consumer fraud in violation of Minn. Stat. §§ 325D.43 *et seq*. and §§ 325F.67 *et seq*.;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Miss. Code Ann. §§ 75-24-1 *et seq*.;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Mo. Ann. Stat. §§ 407.010 *et seq*.;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Mont. Code Ann. §§ 30-14-101 *et seq*.;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Neb. Rev. Stat. §§ 59-1601 *et seq*.;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Nev. Rev. Stat. §§ 598.0903 *et seq*.;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:1 *et seq*.;

ee. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or trade practices in violation of N.J. Rev. Stat. §§ 56:8-1 *et seq*.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of N.M. Stat. §§ 57-12-1 *et seq*.;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of N.Y. Gen. Bus. Law §§ 349 *et seq*. and §§ 350-e *et seq*.;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of N.C. Gen. Stat. §§ 75-1.1 *et seq*.;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of N.D. Cent. Code §§ 51-12-01 *et seq*. and §§ 51-15-01 *et seq*.;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Ohio Rev. Code Ann. §§ 1345.01 *et seq*.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or made false representations in violation of Okla. Stat. tit. 15 §§ 751 *et seq*.;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Or. Rev. Stat. §§ 646.605 *et seq*.;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of 73 Pa. Stat. §§ 201-1 *et seq*.;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of R.I. Gen. Laws. §§ 6-13.1-1 *et seq*.;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of S.C. Code Ann. §§ 39-5-10 *et seq*.;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of S.D. Codified Laws §§ 37-24-1 *et seq*.;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Tenn. Code Ann. §§ 47-18-101 *et seq*.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Tex. Bus. & Com. Code Ann. §§17.41 *et seq*.;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Utah Code Ann. §§ 13-11-1 *et seq*.;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Vt. Stat. Ann. tit. 9, §§ 2451 *et seq*.;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Va. Code Ann. §§ 59.1-196 *et seq*.;

vv. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or trade practices in violation of Wash. Rev. Code. §§ 19.86.010 *et seq*.;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of W. Va. Code §§ 46A-6-101 *et seq*.;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Wis. Stat. §§ 100.20 *et seq*.; and

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices in violation of Wyo. Stat. Ann. §§ 40-12-101 *et seq*.

321. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Devices. Each aspect of Defendants' conduct combined to artificially create sales of the Devices.

322. The medical community relied upon Defendants' misrepresentations and omissions in determining which cardiac device to utilize.

323. By reason of the unlawful acts engaged in by Defendants, Plaintiffs have suffered ascertainable loss and damages.

324. Plaintiffs have provided or will provide any required notice to appropriate entities and authorities regarding Defendants' unfair and deceptive trade practices.

325. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs were damaged by paying in whole or in part for these Devices.

326. As a direct and proximate result of Defendants' violations of state consumer protection statutes, Plaintiffs have sustained economic losses and other damages for which they are entitled to statutory, compensatory damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and injunctive relief to which Plaintiffs are entitled by law.

COUNT IX
THE SENIOR CITIZEN AND HANDICAPPED PERSON CONSUMER FRAUD ACT MINNESOTA STATUTE § 325F.71 AND/OR SIMILAR STATUTES IN EFFECT IN OTHER JURISDICTIONS

327. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein..

328. Pursuant to Minn. Stat. § 325F.71(2), this Count only applies to those Plaintiffs who are Senior Citizens and/or Handicapped persons.

329. Minn. Stat. § 325F.71, subdiv. 2 incorporates Minn. Stat. § 325D.43-48 regarding deceptive trade practices, § 325F.67 regarding false advertising and § 325F.68-70 regarding consumer fraud and provides special remedies if violations of those statutes are directed against senior citizens or handicapped people, including priority of restitution § 325F.71 subdiv. 3 and the recovery of "damages, including costs of investigation and reasonable attorney's fees" and to

"receive other equitable relief as determined by the court." *Id.* § 325F.71 subdiv. 4. Similar statutes are in effect in other States which provide for either relief and/or trial preferences.

330. The affirmative misrepresentations and the pattern of omissions by Defendants described above, violated Minn. Stat. § 325F.44, subdiv. 1, (5) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Devices had "characteristics, ingredients, uses [and/or] benefits . . . that they do not have" a per se violation of § 325F.71.

331. The affirmative misrepresentations and the pattern of omissions by Defendants described above, violated § 325F.44, subdiv. 1, (6) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Devices were original or new when they were, in fact, "deteriorated" as described in the June 17, 2005 "Urgent Medical Device Safety Information & Corrective Action" recall letter to doctors, a per se violation of § 325F.71.

332. The affirmative misrepresentations and the pattern of omissions by Defendant described above, violated Minn. Stat. § 325F.44, subdiv. 1, (7) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Devices were of a "particular standard, quality or grade", when they were, in fact, of a much lower standard, quality or grade, a per se violation of § 325F.71.

333. The affirmative misrepresentations and the pattern of omissions by Defendants in their Annual Reports, advertising literature, press releases and other public statements, constitutes false advertising as prohibited by § 325F.67, a per se violation of § 325F.71.

334. The conduct, affirmative misrepresentations, and the pattern of omissions by Defendant described above constitutes a "fraud, false pretense, false promise, misrepresentation,

misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of . . . [the Devices]", in violation of Minn. Stat. § 325F.69, subdiv. 1, a per se violation of § 325F.71.

335. Pursuant to Minn. Stat. § 325F.71 subdiv. 4, Plaintiffs are entitled to recover all damages arising out of Defendants' violation of Minn. Stat. § 325F.44, subdiv. 1, (5), (6) and/or (7); § 325F.67 and/or Minn. Stat. § 325F.69, subdiv. 1.

336. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses, and other damages for which they are entitled to statutory, compensatory, and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special, and equitable relief to which Plaintiffs are entitled by law

337. In addition, Plaintiffs are entitled to recover "costs of investigation and reasonable attorney's fees", pursuant to Minn. Stat. § 325F.71, subdiv. 4 and the court is urged to give priority to the remedy of restitution pursuant to Minn. Stat. § 325F.71, subdiv. 3.

338. Plaintiffs have provided or will provide any required notice to appropriate entities regarding Defendants' wrongful conduct against senior citizens and handicapped persons and will do so as well under other State's laws of similar effect.

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

339. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections; and the Negligence Count of Plaintiffs' Complaint as if fully set forth herein.

340. Defendants carelessly and negligently manufactured, marketed, and sold the Devices to Plaintiffs, carelessly and negligently concealed these defects from Plaintiffs, and carelessly and

negligently misrepresented the quality, safety, and usefulness of the Devices. Defendants should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons, that might, in turn, result in illness or bodily harm.

341. Defendants owed a duty to treating physicians and ultimate End Users of the Devices, including Plaintiffs, to accurately and truthfully represent the risks of the Devices. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of the Devices – effects of which Defendants knew or in the exercise of diligence should have known – to the treating physicians and Plaintiffs.

342. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, Plaintiffs have sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury or death and are entitled to recovery of damages in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

343. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections; and the intentional wrongdoing allegations of Plaintiffs' Complaint as if fully set forth herein.

344. Defendants' conduct directed toward Plaintiffs, was, by act and omission, intentional, knowing, and/or reckless, and evidenced a willful intention to inflict injury upon Plaintiffs, or a reckless disregard for the rights and interests of Plaintiffs equivalent to an intentional violation of them. This conduct exceeded all bounds usually tolerated by decent and civilized society and was directed toward an inherently vulnerable population of cardiac patients.

345. As a direct, proximate, intended, known, natural, and foreseeable result of Defendants' conduct, Plaintiffs were and are suffering injury in the form of serious, severe, extreme and/or disabling emotional distress that no reasonable person could or should be expected to endure.

346. Defendants are liable and accountable at law to compensate Plaintiffs for such emotional distress, and for all such damages and injuries resulting therefrom and related thereto.

347. Defendants' conduct was intentional, knowing, oppressive, fraudulent, malicious, extreme and outrageous, and done in conscious and reckless disregard of Plaintiffs' rights, thereby entitling Plaintiffs to seek to assert claims for exemplary and punitive damages, at the appropriate time under governing law, in an amount sufficient, necessary and appropriate to punish Defendants for their reprehensible conduct and to deter them and others from such conduct in the future. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XII
GROSS NEGLIGENCE/MALICE

348. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

349. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct:

was specifically intended to cause substantial injury to Plaintiffs; or

when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others,

and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or

included a material representation that was false, with Defendants knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

350. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will, as noted, seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XIII
LOSS OF CONSORTIUM

351. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

352. At all times relevant hereto the Plaintiffs spouses (hereinafter referred to as "Spouse Plaintiffs") and/or family members (hereinafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of Plaintiffs' injuries.

353. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

354. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love, and affection.

355. For all Spouse Plaintiffs, Plaintiff alleges his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

356. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

357. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs jointly and/or severally for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

COUNT XIV
WRONGFUL DEATH

358. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

359. Decedent Plaintiffs died as a result of defects in Defendants' Devices and are survived by various family members, named and unnamed.

360. The representatives/administrators of Decedent Plaintiffs' estate bring this claim on behalf of the Decedent Plaintiffs' lawful heirs.

361. Defendants' wrongful conduct has proximately caused Decedent Plaintiffs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love and consortium.

362. Decedent Plaintiffs' estate representative brings this claim on behalf of Decedent Plaintiffs' lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

363. Decedent Plaintiffs' estate representative further pleads all wrongful death damages allowed by statute in the state or states in which the causes of action accrued.

COUNT XV
SURVIVAL ACTION

364. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

365. As a direct and proximate result of the conduct of Defendants outlined above, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to Decedent Plaintiffs' deaths.

366. The representatives/administrators of Decedent Plaintiffs' estate bring this claim on behalf of Decedent Plaintiffs' estate and Decedent Plaintiffs' beneficiaries for damages.

367. The representatives/administrators of Decedent Plaintiffs' estate further plead all survival damages allowed by statute in the state or states in which the causes of action accrued.

COUNT XVI
MEDICAL MONITORING

368. Plaintiffs hereby incorporate by reference all paragraphs of Plaintiffs' Complaint as if fully set forth herein.

369. As a result of Defendants' negligence or intentional or reckless wrongdoing as set forth hereinabove, which caused Plaintiffs' implantation with and utilization of the Devices, Plaintiffs were and are injured and/or were and are directly exposed on a prolonged, repeated and continuous basis, to a significantly and substantially increased risk of injury and death from failure or malfunction of the Devices, relative to the population of cardiac patients implanted with non-defective and unrecalled devices or receiving other therapies. Plaintiffs thus require increased medical monitoring in addition to that normally required for pacemaker and defibrillator patients, in order to detect, prevent, ameliorate, and reduce the risk of injury, further injury, or death.

370. Defendants are responsible and accountable at law and in equity for this exposure to and substantially increased risk of harm, injury, and death; and are therefore liable to fund and pay for a comprehensive, Court-supervised program of medical monitoring and surveillance, diagnosis, and ongoing research, designed to eliminate or ameliorate further injury and harm, whether such relief is denominated or characterized under applicable law as declaratory, injunctive, or equitable relief; or as damages. Among the remedies that are reasonable and necessary, and can be specifically designed to increase the safety and guard the health of Plaintiffs, and that should be implemented at Defendants' expense, is a comprehensive Device registry system that promptly and timely alerts patients and their doctors to recalls and warnings, as well as other remedies and monitoring which Defendants themselves have acknowledged, such as, if appropriate, testing shocks for devices and extra-monitoring.

COUNT XVII
UNJUST ENRICHMENT

371. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

372. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and implementation of Defendants' Devices by Plaintiffs.

373. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants, or that Plaintiffs, as reasonable consumers, expected to receive.

374. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

CLAIMS FOR RELIEF
THIRD PARTY PAYOR PLAINTIFFS

375. Counts XVIII through XXXI, below, are asserted on behalf of the Third Party Payor Plaintiffs and are subject to the reservations set forth in paragraph 31, above. As used in these Counts the term "Plaintiffs" refers to Third Party Payor Plaintiffs.

COUNT XVIII
VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICE ACT

376. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

377. Defendants applied advertising and marketing campaigns representing the Devices as mechanically sound and medically safe, while they knew of the defects in the devices.

378. Defendants knew or should have known of the defective nature of the Devices but denied public access to the information, to avoid corporate responsibility. Defendants knew their patients and their physicians were at a disadvantage in accessing information involving the safety of their affected devices.

379. Defendants concealed the design defects of their device for the purposes of higher profits and increased sales.

380. Defendants have violated Minn. Stat. §325D.44. The violations include the following.

381. Defendants have violated Minn. Stat. §325D.44 (5) by representing the Devices as having characteristics, uses, and benefits of a safe and mechanically sound device while knowing the statements were false and the devices contained inherent design defects.

382. Defendants have violated Minn. Stat. § 325D.44 (7) by representing the Devices as a non-defective medical product of a particular standard, quality, or grade while knowing the statements were false and the devices contained inherent design defects.

383. Defendants have violated Minn. Stat. § 325D.44 (9) by advertising, marketing, and selling the Devices as medically reliable and without a known design defect while knowing those claims were false and without any medical support.

384. Defendants have violated Minn. Stat. § 325D.44 (13) by creating a likelihood of confusion about the efficacy and mechanical soundness of their medical device, comparing the Devices with other non-defective products.

385. The Minnesota statutes prohibiting unfair and deceptive trade practices apply because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs and

other Third Party Payors whose beneficiaries were implanted with the Devices containing the known defects.

386. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Third Party Payors have incurred health care costs related to the Devices that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

COUNT XIX
VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

387. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

388. Defendants intentionally concealed their design defect and failed to disclose for the purposes of continuing the sale and distribution of the Devices.

389. Defendant represented that the Devices were safe and effective and intended that patients and physicians rely on those representations when deciding if Defendant's device was optimal for meeting the patient's needs.

390. Through these misleading and deceptive statements and false promises, Defendant violated Minn. Stat. § 325F.69.

391. The Minnesota statutes prohibiting consumer fraud apply to all of Defendant's transactions with Plaintiffs and other third party payer beneficiaries implanted with the Devices because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiffs and other Third Party Payors.

392. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Third Party Payors have incurred health care costs related to the Devices which have been paid by them, but are the responsibility of Defendants, in an amount to be proven at trial.

COUNT XX
VIOLATION OF MINNESOTA FALSE STATEMENTS IN ADVERTISING STATUTE

393. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

394. Defendants produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Devices after learning of their inherent defects with the intent to sell the Devices.

395. Defendants concealed their deceptive practices in order to increase the sale of and profit from the Devices.

396. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the Minnesota False Statements in Advertising Statute, Minn. Stat. § 325F.67 *et seq*., when the failed to comply with FDA regulations and when they failed to adequately warn consumers and the medical community of the safety risks associated with the Devices. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 *et seq*., Plaintiffs and the TPP Class were injured in that they paid substantial sums for the Devices and for the costs of replacing the Devices that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

397. Defendants systematically and continually conducts business throughout the state of Minnesota in that (1) they maintain offices in Minnesota and the CRM Division is headquartered in the state; (2) Defendants' CRM facilities operate in Minneapolis, Minnesota, which is the CRM Division's principal place of business for manufacturing, research and development, administration, marketing and sales, warehousing, packaging, and shipping of the Devices; and (3) the market, advertise, and sell the Devices within Minnesota.

398. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other Third Party Payors have incurred health care costs related to the Devices that have been paid by them but are the responsibility of Defendants, in an amount to be determined at trial.

COUNT XXI
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

399. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

400. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the Devices.

401. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs and members of the Class would not have purchased and/or paid for the Devices, and would not have incurred related medical costs.

402. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs and TPP Class members, constituted unfair and deceptive acts and practices in violation of the state consumer protection statutes listed below.

403. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff and TPP Class members for the Devices and for the costs of replacing the Devices that they would not have paid had Defendant not engaged in unfair and deceptive conduct.

404. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes, as listed below:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §1770, *et seq*. and Cal. Bus. & Prof. Code § 17200, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110a, *et seq.*;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §§ 2511, *et seq.* and 2531, *et seq*.;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §§10-1-372, *et seq.*, 10-1-392 and 10-1-420.

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.170, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 205A, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann.. § 445.901, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325D.43, *et seq.*;, 325F.67, *et seq.*; and 325F.68 *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Ann. Missouri Stat. § 407.010, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann. § 30-14-101, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. § 598.0903, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§ 349 *et seq.* and 350-e, *et seq*.;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§ 51-12-01, *et seq*., and 51-15-01*, et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, *et seq.*; and

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-101, *et seq.*

405. Plaintiffs and the TPP Class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Devices. Each aspect of Defendants' conduct combined to artificially create sales of the Devices.

406. The medical community, including Plaintiffs and TPP Class members, relied upon Defendants' misrepresentations and/or omissions in determining which cardiac device to utilize.

407. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and other Third Party Payors have suffered ascertainable loss and damages.

408. Plaintiffs have provided or will provide any required notice to appropriate entities regarding Defendants' unfair and deceptive trade practices.

409. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Third Party Payors were damaged by paying for these devices.

410. As a direct and proximate result of Defendants' conduct, Plaintiffs and the TPP Class have incurred and will likely incur full or partial costs for Devices and related medical costs including implantation surgery, replacement cardiac devices, replacement surgery, medical monitoring and/or other hospital costs, in an amount to be proven at trial.

411. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the TPP Class are entitled to compensatory damages, treble damages, attorneys' fees, and costs of suit.

COUNT XXII
SUBROGATION LIABILITY DETERMINATION

412. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

413. Throughout the relevant period, Plaintiffs and the TPP Class provided a full spectrum of health benefit products, including, but not limited to, managed care products, third party administration services, and indemnity products to groups and individuals on both an insured and an employer funded basis. Each of these products was provided to members injured by the Devices.

414. The damages sustained by Plaintiff and the TPP Class include but are not limited to damages for all benefits paid for or provided to plan members or insureds, said damages being incurred as a result of the plan members or insureds being injured by or seeking treatment as a proximate result of utilization of the Devices.

415. Plaintiffs and the TPP Class provided these and other benefits to their insureds and plan members not as volunteers but pursuant to their obligations under contractual agreements specifying the respective rights and obligations of the Plaintiffs and the Class and their members or insureds. These agreements specifically grant Plaintiffs and the Class broad subrogation and reimbursement rights.

416. Plaintiffs and the TPP Class provided benefits to their plan members and insureds and possess subrogation and reimbursement rights per either contractual provisions granting each of them such or equitable subrogation under the substantive law of the jurisdictions in which they are located and in which Defendants sold their products.

417. Plaintiffs and the TPP Class have contractual and equitable rights of subrogation and reimbursement against Defendants to recover damages to the extent of health benefits paid or provided on behalf of members, employees and insureds implanted with the Devices.

418. As a result of their subrogation and reimbursement rights, Plaintiffs and the TPP Class hereby seek injunctive relief in the form of creation of a class under Fed. R. Civ. P. 23(b)(2) or other applicable law for a classwide determination of Defendants' and, if appropriate, the Device Recipient Plaintiffs, liability as well as disclosure by Defendants of records sufficient (and solely) for purposes of identifying insured, employees or members for whom Plaintiffs and the TPP Class have subrogation or reimbursement claims.

COUNT XXIII
UNJUST ENRICHMENT

419. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

420. To the detriment of Plaintiffs and TPP Class members, Defendants have been, and continue to be unjustly enriched as a result of the unlawful and/or wrongful collections of, *inter alia*, payments for the Devices and associated costs.

421. In exchange for the payments made for the Devices, and at the time they made these payments, Plaintiffs and the Class expected that the Devices were safe and medically effective treatment for the condition, disorder, or symptom for which they were prescribed.

422. The cumulative effect of Defendants' conduct directed at physicians and consumers was to artificially create demand for Devices. Plaintiffs and the TPP Class were injured by the cumulative and indivisible nature of Defendants' conduct.

423. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs and the TPP Class

made for the Devices and from payments Plaintiffs and the TPP Class have made for replacements for the Devices.

424. In exchange for the payments they made for the Devices, and at the time they made these payments, Plaintiffs and the TPP Class expected that the Devices were safe and medically effective treatment for the condition, illness, disorder, or symptom for which they were prescribed.

425. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and the TPP Class paid for the Devices and were forced to pay for replacement devices when they otherwise would not have done so. The failure of Defendants to provide Plaintiffs and the TPP Class with the remuneration they expected enriched Defendants unjustly.

426. Plaintiffs and the TPP Class are entitled in equity to seek restitution of Defendants' wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

427. Accordingly, Plaintiffs and the TPP Class seek full restitution of Defendants' enrichment, profits, revenues, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

COUNT XXIV
BREACH OF IMPLIED WARRANTY

428. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

429. Prior to the time that beneficiaries of Plaintiffs and other third party payers were implanted with the Devices, Defendants impliedly warranted to them that the Devices were of merchantable quality and safe and fit for the use for which they were intended.

430. Plaintiffs and other Third Party Payors were and are unskilled in the research, design and manufacture of the Devices, and reasonably relied entirely on the skill, judgment, and implied warranty of Defendants in allowing the implantation of the Devices.

431. Defendants breached the implied warranty for the Devices because said devices were defective, unmerchantable, and not fit for their intended purpose.

432. As a direct and proximate result of Defendants' breaches of warranties, Plaintiffs and other Third Party Payors have incurred health care costs related to the Devices that have been paid by them, but are the responsibility of Defendants, in an amount to be proven at trial.

COUNT XXV
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

433. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of the Master Complaint as if fully set forth herein.

434. Defendants have acknowledged their obligation as first party insurers by providing express and implied warranties directly to consumers of their products, and specifically the recalled devices.

435. Defendants have an obligation to repay Plaintiffs and the Class for all costs incurred with the Devices because they have acknowledged a responsibility under their warranties to make payment with regard to the recalled devices.

436. As a direct and proximate result of Defendants' breaches of their assumed contractual duties, Plaintiffs and other Third Party Payors have incurred health care costs related to the Devices that have been paid by them, but are the responsibility of Defendants, in an amount to be proven at trial.

COUNT XXVI
MISREPRESENTATION BY OMISSION

437. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

438. Defendants misrepresented the mechanical soundness and reliability of the Devices through promotional and marketing campaigns. Defendants continued this misrepresentation for an extended period of time, without disclosing material information.

439. Defendants took advantage of the limited opportunity beneficiaries of Plaintiffs and other Third Party Payors (and their physicians) had to discover Defendant's intentional concealment of the defects and risks in the Devices.

440. Defendants concealed these design defects by withholding information pertaining to the inherent design defects and high risks of failure relating to the Devices, and presenting the devices as safe and reliable.

441. Defendants' intentional misrepresentations and omissions were made willfully, wantonly or recklessly to the beneficiaries of Plaintiffs and Third Party Payers (by among other things through physicians) to induce purchase of the Devices over their competitors.

442. Defendants knew or should have known of the high risk beneficiaries of Plaintiffs and other Third Party Payors would encounter by unwittingly agreeing to have implanted the Devices.

443. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Third Party Payors have incurred health care costs related to the Devices that have been paid by them, but are the responsibility of Defendants, in an amount to be proven at trial.

CLAIMS FOR RELIEF
MEDICARE SECONDARY PAYOR PLAINTIFFS

444. Counts XXVII through XXX, below, are asserted on behalf of the Medicare Secondary Payor Plaintiffs and are subject to the reservations set forth in paragraph 31, above. As used in these Counts the term "Plaintiffs" refers to Medicare Secondary Payor Plaintiffs.

COUNT XXVII
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

445. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

446. Defendants have acknowledged their obligations as first-party insurer by providing express and/or implied warranties directly to consumers of their products, and specifically the Devices.

447. Defendants have an obligation to repay Plaintiffs for all costs incurred with the Devices because they have acknowledged a responsibility under their warranties to make payment with regard to the Devices.

448. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages including health care costs that have been paid by them in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law.

COUNT XXVIII
LIABILITY AS FIRST-PARTY INSURER UNDER MSP: AGREEMENT TO PAY MEDICAL COSTS

449. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

450. Defendants are a first-party insurer under the MSP as courts have interpreted that statute from time to time.

451. Defendants have acknowledged their obligations as first party insurer by agreeing to pay medical costs incurred in connection with the Devices.

452. By Defendants' acknowledgement of their obligation to pay such medical costs, it is a primary plan within the meaning of 42 U.S.C. § 1395y(b)(2)(A).

453. Defendants have an obligation to repay Medicare for all costs incurred with the Devices because they have acknowledged a responsibility to make payment with regard to the Devices, as required by 42 U.S.C. § 1395y(b)(2)(B)(ii).

454. A private cause of action for such recovery is provided by 42 U.S.C. § 1395y(3)(A) because Defendants have failed and refused to make the payments required by 42 U.S.C. § 1395y(b)(2)(A).

455. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages including health care costs that have been paid by them in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law, including mandatory double damages pursuant to 42 U.S.C. § 1395y(3)(A).

COUNT XXIX
LIABILITY AS FIRST-PARTY INSURER UNDER MSP: PROVISION OF EXPRESS AND IMPLIED WARRANTIES

456. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

457. Defendants are a first-party insurer under the MSP as courts have interpreted that statute from time to time.

458. Defendants have acknowledged their obligations as first-party insurer by providing express and/or implied warranties directly to consumers of their products, and specifically the Devices.

459. By Defendants' provision of implied warranties, they are a primary plan within the meaning of 42 U.S.C. § 1395y(b)(2)(A).

460. Defendants have an obligation to repay Medicare for all costs incurred with the Devices because they have acknowledged a responsibility under their warranties to make payment with regard to the Devices, as is required by 42 U.S.C. § 1395y(b)(2)(B)(ii).

461. A private cause of action for such recovery is provided by 42 U.S.C. § 1395y(3)(A) because Defendants have failed and refused to make the payments required by 42 U.S.C. § 1395y(b)(2)(A).

462. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages including health care costs that have been paid by them in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law, including mandatory double damages pursuant to 42 U.S.C. § 1395y(3)(A).

COUNT XXX
LIABILITY AS THIRD PARTY INSURER UNDER MSP: LIABILITY AS HOLDER OF A LIABILITY INSURANCE POLICY OR PLAN

463. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

464. Defendants are a third party insurer under the MSP as courts have interpreted that statute from time to time.

465. Defendants maintain liability insurance policies, or are self-insured, from which payments for medical costs are made once liability has been established.

466. Defendants have liability for damages incurred in connection with their Devices. This liability is predicated on each and every count as alleged in the claims raised by personal injury claimants and by third party payer claimants. All such claims and counts are incorporated herein by reference.

467. As a result of such liability, Defendants' liability policies and/or their self-insured plans are a primary plan within the meaning of 42 U.S.C. § 1395y(b)(2)(A).

468. Defendants have an obligation to repay Medicare for all costs incurred with the Devices because they maintain liability insurance policies, as set forth in 42 U.S.C. § 1395y(b)(2)(B)(ii).

469. A private cause of action for such recovery is provided by 42 U.S.C. § 1395y(3)(A) because Defendants have failed and refused to make the payments required by 42 U.S.C. § 1395y(b)(2)(A).

470. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have suffered damages including health care costs that have been paid by them in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and/or severally for all general, special and equitable relief to which Plaintiffs are entitled by law, including mandatory double damages under pursuant to 42 U.S.C. § 1395y(3)(A).

COUNT XXXI
PUNITIVE DAMAGES

471. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

472. Pursuant to the Stipulation of the Parties and this Court's Pretrial Order 28 of February 6, 2007, Plaintiffs assert, *nunc pro tunc* as of April 24, 2006, that Defendants' actions warrant the imposition of punitive and/or exemplary damages under law and in amount to be determined at trial, as well as the other relief set forth below and above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment against Defendants as follows:

1. For an Order certifying the Classes and any appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Plaintiffs and their counsel to represent such Classes and subclasses as appropriate under Rule 23(g);

2. For the equitable relief requested;

3. For compensatory damages according to proof;

4. For punitive or exemplary damages against Defendants, at the appropriate time under governing law as determined by the Court, consistent with the degree of Defendants' reprehensibility and the resulting harm or potential harm to Plaintiffs and the Class, and in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

5. For all applicable statutory damages under the consumer protection legislation of all states and the District of Columbia;

6. For declaratory judgment that Defendants are liable to Plaintiffs and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants' wrongdoing;

7. For medical monitoring, whether denominated as damages or in the form of equitable relief;

8. For notice to be disseminated to all Class members of the defect who have been implanted with the Devices;

9. For a disgorgement of profits and restitution of all costs related to the Devices;

10. For an award of damages in an amount double the amount paid by Medicare to reimburse health care providers for all health care services provided to all Medicare beneficiaries resulting from the recalled Devices, which expenditures Defendants were required or responsible to make under the Medicare Secondary Payer Statute;

11. For an award of attorneys' fees and costs;

12. For prejudgment interest and the costs of suit;

13. For such other and further relief as this Court may deem just and proper; and

14. For preference in setting the matter for trial pursuant to Cal. Civ. Proc. Code § 36; Fla. Stat. § 415.1115; 735 Ill. Comp. Stat. 5/2-1007.1; La. Code Civ. Proc. art. 1573; and N.Y. CPLR 3403.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.

Date: February 21, 2007

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